

Medicare Fraud & Abuse

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PART I

Medicare Administration

Medicare is vulnerable to fraud, waste, abuse, and improper payments (payments that should not have been made or were made in an incorrect amount). Medicare is considered high-risk in part because of its complexity and susceptibility to improper payments, and because of concerns about the adequacy of its fiscal oversight to prevent inappropriate spending. In fiscal year 2016, the Centers for Medicare & Medicaid Services (CMS)—the agency that administers Medicare and Medicaid—estimated that Medicare made a total of over \$40 billion in improper payments (Medicare Fee-for-Service 2016 Improper Payments Report). The Medicaid program overpayment's exceeded \$50 billion in 2015 (Medicaid and CHIP 2015 Improper Payments Report).

Medicare Overview

Everyone with an insurance license should be familiar with the basics of Medicare. The text now turns to information which should serve as a primer in the basics of Medicare. Medicare is a social insurance program administered by the United States government, providing health insurance coverage to people who are aged 65 and over, or who meet other special criteria. The program also funds residency training programs for the vast majority of physicians in the United States. Medicare operates as a single-payer health care system.

Selling Medicare-Related Products

State departments of Insurance require specific continuing education for persons marketing Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, and Prescription Drug Plans. This requirement is necessary to maintain effective regulation of the insurance industry by safeguarding senior citizens and other individuals eligible for Medicare plans (Medicare beneficiaries) who are confronting significant healthcare decisions. The Centers for Medicare & Medicaid Services (CMS) Guidelines and now the Medicare Improvements for Patients and Providers Act of 2008, Public Law 110 – 275 (MIPPA) §103(d)(1), which amends §1851(h) of the Social Security Act (42 U.S.C. 1395w–21(h)), require that Medicare Advantage organizations only use agents who have been licensed under state law to market Medicare plans.

The regulations use the term *market* rather than *sell* with respect to licensed agents because *marketing* is used in the CMS Marketing guidelines and fully encompasses the concept of *soliciting*, which is a primary function of an agent.

Single-Payer System

The financing of the costs of delivering health care for an entire population through a single insurance pool out of which costs are met describes a “single-payer” system. It is a form of monopsony, a market form in which only one buyer faces many sellers. It is an

example of imperfect competition, similar to a monopoly. There may be many contributors to the single pool (insured persons, employers, government, etc. Single-payer health insurance collects all medical fees and then pays for all services through a single government (or government-related) source. The Medicare program is an example of a single-payer system for a specified, limited group of persons.

The Centers for Medicare and Medicaid Services (CMS), a component of the Department of Health and Human Services (HHS), administers Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), and the Clinical Laboratory Improvement Amendments (CLIA). Along with the Departments of Labor and Treasury, CMS also implements the insurance reform provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Social Security Administration is responsible for determining Medicare eligibility and processing premium payments for the Medicare program.

The Chief Actuary of CMS is responsible for providing accounting information and cost-projections to the Medicare Board of Trustees to assist them in assessing the financial health of the program. The Board is required by law to issue annual reports on the financial status of the Medicare Trust Funds, and those reports are required to contain a statement of actuarial opinion by the Chief Actuary.

Since the beginning of the Medicare program, CMS has contracted with private companies to operate as intermediaries between the government and medical providers. These contractors are commonly already in the insurance or health care area. Contracted processes include claims and payment processing, call center services, clinician enrollment, and fraud investigation.

Taxes imposed to finance Medicare

Medicare is partially financed by payroll taxes imposed by the Federal Insurance Contributions Act (FICA) and the Self-Employment Contributions Act of 1954. Taxes pay for current government programs.

In the case of employees, the tax is equal to 2.9% (1.45% withheld from the worker and a matching 1.45% paid by the employer) of the wages, salaries and other compensation in connection with employment. Until December 31, 1993, the law provided a maximum amount of compensation on which the Medicare tax could be imposed each year. Beginning January 1, 1994, the compensation limit was removed. A self-employed individual must pay the entire 2.9% tax on self employed net earnings, but may deduct half of the tax from the income in calculating income tax. In 2013, the 2.9% hospital insurance tax increased to 3.8% for individuals making over \$200,000 or jointly filing couples making in excess of \$250,000.

Pay-As-You-Go

Payment of taxes today does not entitle a taxpayer to services in years to come; a common misconception about benefits under Social Security, Medicare, and other government programs. PAYGO is the practice of financing expenditures with funds that are currently available rather than borrowed. The Part A program is financed on a "pay-as-you-go" basis, with taxes paid into the program being used to pay for the benefits

received by current retirees, and the excess used to reduce the federal deficit. Medicare Part B is financed largely by payments from federal general revenues supplemented by premiums that beneficiaries pay calculated to cover only about 25% of the outlays. The “pay-as-you-go” financing of Part A is similar to a chain letter in that it promises future benefits to those who fund services for current beneficiaries, and there is a continual need for a growing number of new contributors to fund the growing number of beneficiaries. Chain letters eventually collapse from an insufficient influx of new participants. Likewise, the number of workers contributing payroll taxes to finance the Part A trust fund is declining.

Eligibility

In general, all persons 65 years of age or older who have been legal residents of the United States for at least 5 years are eligible for Medicare. However, if neither they nor their spouse have paid Medicare taxes for a minimum of 10 years (40 quarters), then they must pay a monthly premium to be enrolled in Medicare. Medicare part 'A' premiums are waived if the following circumstances apply:

- They are 65 years or older **and** U.S. citizens or have been permanent legal residents for 5 continuous years, **and** they or their spouse has paid Medicare taxes for at least 10 years.

or

- They are under 65, disabled, and have been receiving either Social Security benefits or the Railroad Retirement Board disability benefits for at least 24 months from date of entitlement (first disability payment).

or

- They get continuing dialysis for end stage renal disease or need a kidney transplant.

or

- They are eligible for Social Security Disability Insurance and have amyotrophic lateral sclerosis (known as ALS or Lou Gehrig's disease).

The 24 month exclusion means that people who become disabled must wait 2 years before receiving government medical insurance, unless they have one of the listed diseases or they are eligible for Medicaid.

Many beneficiaries are dual-eligible. This means they qualify for both Medicare and Medicaid. In some states for those making below a certain income, Medicaid will pay the beneficiaries' Part B premium for them (most beneficiaries have worked long enough and have no Part A premium), and also pay for any drugs that are not covered by Part D.

In 2015, Medicare provided health care coverage for 55 million Americans, making it the largest single health care payer in the nation. Enrollment is expected to reach 78 million by 2030.

Benefits

Medicare has four parts: Part A is Hospital Insurance. Part B is Medical Insurance. Medicare Part D covers prescription drugs. Medicare Advantage plans, also known as Medicare Part C, are another way for beneficiaries to receive their Part A, B and D

benefits. All Medicare benefits are subject to medical necessity. The original program was only Parts A and B. Part D was new in January 2006; before that, Parts A and B covered prescription drugs in only a few special cases.

Part A: Hospital Insurance

Part A covers inpatient hospital stays (at least overnight), including semiprivate room, food, tests, and doctor's fees. Part A covers brief stays for convalescence in a skilled nursing facility if certain criteria are met:

1. A preceding hospital stay must be at least three days, three midnights, not counting the discharge date.
2. The nursing home stay must be for something diagnosed during the hospital stay or for the main cause of hospital stay.
3. If the patient is not receiving rehabilitation but has some other ailment that requires skilled nursing supervision then the nursing home stay would be covered.
4. The care being rendered by the nursing home must be skilled. Medicare part A does not pay for custodial, non-skilled, or long-term care activities, including activities of daily living (ADL) such as personal hygiene, cooking, cleaning, etc.

The maximum length of stay that Medicare Part A will cover in a skilled nursing facility per ailment is 100 days. The first 20 days would be paid for in full by Medicare with the remaining 80 days requiring a co-payment (as of 2017, \$164.50 per day). Many insurance companies have a provision for skilled nursing care in the policies they sell. If a beneficiary uses some portion of their Part A benefit and then goes at least 60 days without receiving facility-based skilled services, the 100-day clock is reset and the person qualifies for a new 100-day benefit period.

Part B: Medical Insurance

Part B medical insurance helps pay for some services and products not covered by Part A, generally on an outpatient basis. Part B is optional and may be deferred if the beneficiary or their spouse is still working. There is a lifetime penalty (10% per year) imposed for not enrolling in Part B unless actively working. Part B coverage begins once a patient meets his or her deductible, then typically Medicare covers 80% of approved services, which the remaining 20% is paid by the patient.

Part B coverage includes physician and nursing services, x-rays, laboratory and diagnostic tests, influenza and pneumonia vaccinations, blood transfusions, renal dialysis, outpatient hospital procedures, limited ambulance transportation, immunosuppressive drugs for organ transplant recipients, chemotherapy, hormonal treatments, and other outpatient medical treatments administered in a doctor's office. Medication administration is covered under Part B only if it is administered by the physician during an office visit.

Part B also helps with durable medical equipment (DME), including canes, walkers, wheelchairs, and mobility scooters for those with mobility impairments. Prosthetic devices such as artificial limbs and breast prosthesis following mastectomy, as well as one pair of eyeglasses following cataract surgery, and oxygen for home use are also covered.

Complex rules are used to manage the benefit, and advisories are periodically issued which describe coverage criteria. On the national level these advisories are issued by CMS, and are known as National Coverage Determinations (NCD). Local Coverage Determinations (LCD) only apply within the multi-state area managed by a specific regional Medicare Part B contractor, and Local Medical Review Policies (LMRP) were superseded by LCDs in 2003.

Part C: Medicare Advantage plans

With the passage of the Balanced Budget Act of 1997, Medicare beneficiaries were given the option to receive their Medicare benefits through private health insurance plans, instead of through the original Medicare plan (Parts A and B). These programs were known as "Medicare+Choice" or "Part C" plans. Pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003, "Medicare+Choice" plans were made more attractive to Medicare beneficiaries by the addition of prescription drug coverage and became known as "Medicare Advantage" (MA) plans. Traditional or "fee-for-service" Medicare has a standard benefit package that covers medically necessary care members can receive from nearly any hospital or doctor in the country. For people who choose to enroll in a Medicare Advantage health plan, Medicare pays the private health plan a capitated rate, or a set amount, every month for each member. Members typically also pay a monthly premium in addition to the Medicare Part B premium to cover items not covered by traditional Medicare (Parts A & B), such as prescription drugs, dental care, vision care and gym or health club memberships. In exchange for these extra benefits, enrollees may be limited in the providers they can receive services from without paying extra. Typically, the plans have a "network" of providers that patients can use. Going outside that network may require permission or extra fees.

Medicare Advantage plans are required to offer coverage that meets or exceeds the standards set by the original Medicare program, but they do not have to cover every benefit in the same way. If a plan chooses to pay less than Medicare for some benefits, like skilled nursing facility care, the savings may be passed along to consumers by offering lower copayments for doctor visits. Medicare Advantage plans use a portion of the payments they receive from the government for each enrollee to offer supplemental benefits. Some plans limit their members' annual out-of-pocket spending on medical care, providing insurance against catastrophic costs over \$5,000, for example. Many plans offer dental coverage, vision coverage and other services not covered by Medicare Parts A or B, which makes them a good value for the health care dollar, if you want to use the provider included in the plan's network or "panel" of providers.

Medicare Advantage Plans that also include Part D prescription drug benefits are known as a Medicare Advantage Prescription Drug plan or a MA-PD. Since 2004, the number of beneficiaries enrolled in private plans has more than tripled from 5.3 million to 17.6 million in 2016. This represents 31% of Medicare beneficiaries. A third of beneficiaries with Part D coverage are enrolled in a Medicare Advantage plan. Medicare Advantage enrollment is higher in urban areas; the enrollment rate in urban counties is twice that in rural counties (22% vs. 10%). Almost all Medicare beneficiaries have access to at least two Medicare Advantage plans; most have access to three or more. Because of the 2003 law's overpayments, the number of organizations offering Fee-for-Service plans

has increased dramatically, from 11 in 2006 to almost 50 in 2008. Eight out of ten beneficiaries (82%) now have access to six or more Private Fee-for-Service plans.

Part D: Prescription Drug plans

Medicare Part D went into effect on January 1, 2006. Anyone with Part A or B is eligible for Part D. It was made possible by the passage of the Medicare Prescription Drug, Improvement, and Modernization Act. In order to receive this benefit, a person with Medicare must enroll in a stand-alone Prescription Drug Plan (PDP) or Medicare Advantage plan with prescription drug coverage (MA-PD). These plans are approved and regulated by the Medicare program, but are actually designed and administered by private health insurance companies. Unlike Original Medicare (Part A and B), Part D coverage is not standardized. Plans choose which drugs (or even classes of drugs) they wish to cover, at what level (or tier) they wish to cover it, and are free to choose not to cover some drugs at all. The exception to this is drugs that Medicare specifically excludes from coverage, including but not limited to benzodiazepines, cough suppressant and barbiturates. Plans that cover excluded drugs are not allowed to pass those costs on to Medicare, and plans are required to repay CMS if they are found to have billed Medicare in these cases. Note that for beneficiaries who are dual-eligible (Medicare and Medicaid eligible) Medicaid may pay for drugs not covered by part D of Medicare, such as benzodiazepines, and other restricted controlled substances.

Neither Part A nor Part B pays for all of a covered person's medical costs. The program contains premiums, deductibles and coinsurance, which the covered individual must pay out-of-pocket. Some people may qualify to have other governmental programs (such as Medicaid) pay premiums and some or all of the costs associated with Medicare.

Premiums

Most Medicare enrollees do not pay a monthly Part A premium, because they (or a spouse) have had 40 or more 3-month quarters in which they paid Federal Insurance Contributions Act taxes. Medicare-eligible persons who do not have 40 or more quarters of Medicare-covered employment may purchase Part A for a monthly premium of:

- \$227.00 per month (2017) for those with 30-39 quarters of Medicare-covered employment, or
- \$413.00 per month (in 2017) for those with fewer than 30 quarters of Medicare-covered employment and who are not otherwise eligible for premium-free Part A coverage.

All Medicare Part B enrollees pay an insurance premium for this coverage; the standard Part B premium for 2017 is \$134.00 per month. An income-based premium plan has been in effect since 2007, wherein Part B premiums are higher for beneficiaries with incomes exceeding \$85,000 for individuals or \$170,000 for married couples. Depending on the extent to which beneficiary earnings exceed the base income, these higher Part B premiums are \$187.50, 267.90, or 348.30 for 2017, with the highest premium paid by individuals earning more than \$214,000, or married couples earning more than \$428,000. Part C and D plans may or may not charge premiums, at the programs' discretion. Part C plans may also choose to rebate a portion of the Part B premium to the member.

Deductible and coinsurance

Part A - For each benefit period, a beneficiary will pay (in 2017):

- A Part A deductible is \$1,316.
- A \$329 per day co-pay for days 61-90 of a hospital stay.
- A \$658 per day co-pay for days 91-150 of a hospital stay, as part of their limited Lifetime Reserve Days.
- All costs for each day beyond 150 days.
- Coinsurance for a Skilled Nursing Facility is \$164.50 per day for days 21 through 100 for each benefit period.
- A blood deductible of the first 3 pints of blood needed in a calendar year, unless replaced. There is a 3 pint blood deductible for both Part A and Part B, and these separate deductibles do not overlap.

Part B - After a beneficiary meets the yearly deductible of \$183.00 (in 2017), they will be required to pay a co-insurance of 20% of the Medicare-approved amount for all services covered by Part B with the exception of most lab services which are covered at 100%. The copay for outpatient mental health which started at 50% was gradually stepped down over several years until it matched the 20% required for other services. They are also required to pay an excess charge of 15% for services rendered by non-participating Medicare providers. The deductibles and coinsurance charges for Part C and D plans vary from plan to plan.

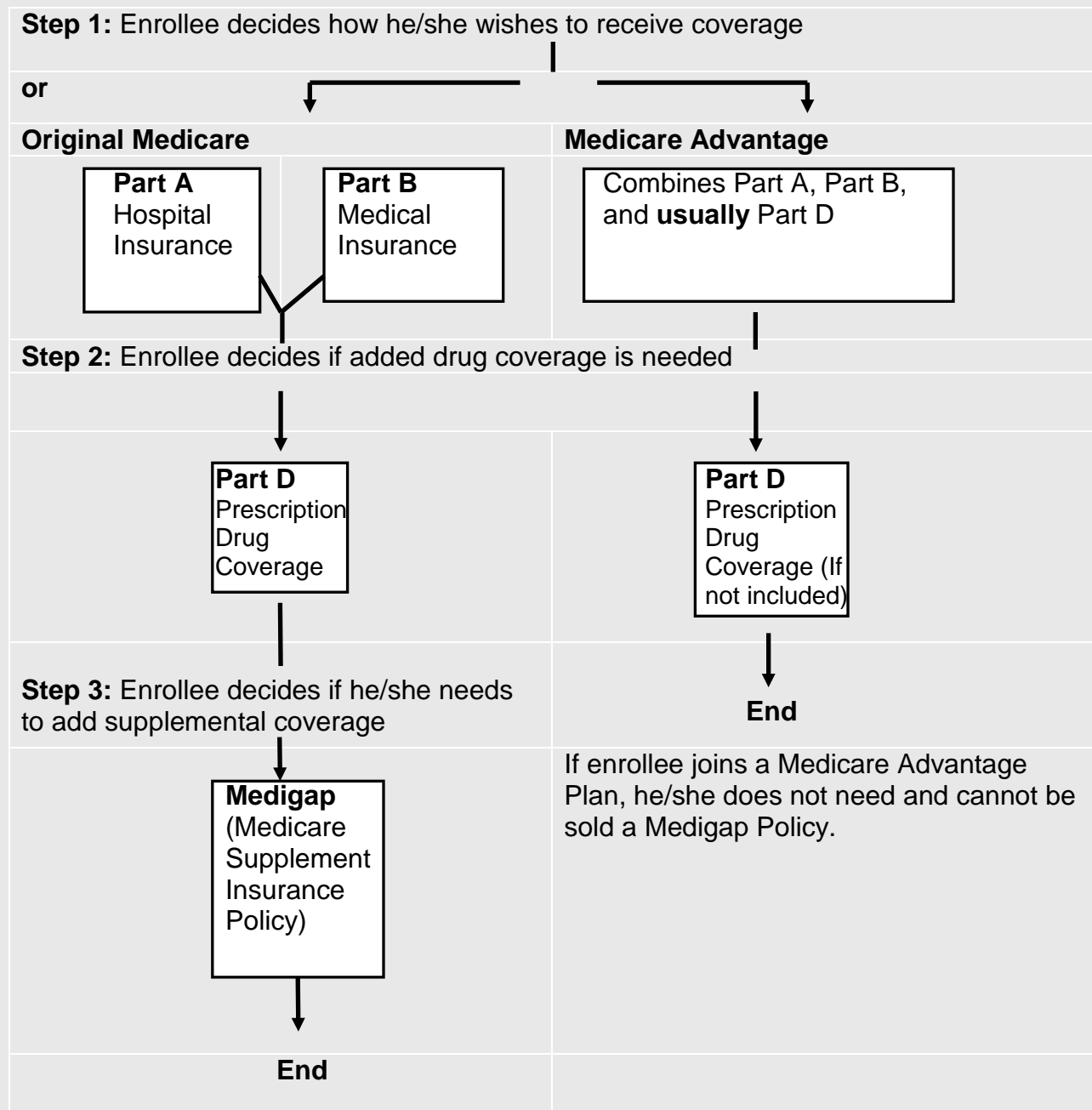
Medicare supplement (Medigap) policies

Some people elect to purchase a type of supplemental coverage, called a Medigap plan, to help fill in the holes in Original Medicare (Part A and B). These Medigap insurance policies are standardized by CMS, but are sold and administered by private companies. Some Medigap policies sold before 2006 may have included coverage for prescription drugs. Medigap policies sold after the introduction of Medicare Part D on January 1, 2006 are prohibited from covering drugs. Medicare regulations prohibit a Medicare beneficiary from having both a Medicare Advantage Plan and a Medigap Policy. Medigap Policies may only be purchased by beneficiaries that are receiving benefits from Original Medicare (Part A & Part B).

Payment for services

Medicare contracts with regional insurance companies who process over one billion fee-for-service claims per year. In 2015, Medicare accounted for 15% (\$540 billion) of the federal budget. Compare this to the \$609 billion for defense funding. For 2016 the Congressional Budget Office projects spending on Medicare to rise to \$591 billion. For the decade 2015-2026 Medicare is projected to cost 9.1 trillion dollars.

Chart 1 Medicare Basics



Medicare Summary

Title XVIII of the Social Security Act, designated “Health Insurance for the Aged and Disabled,” is commonly known as Medicare. As part of the Social Security Amendments of 1965, the Medicare legislation established a health insurance program for aged persons to complement the retirement, survivors, and disability insurance benefits under Title II of the Social Security Act. When first implemented in 1966, Medicare covered most persons aged 65 or older. In 1973, the following groups also became eligible for Medicare benefits: persons entitled to Social Security or Railroad Retirement disability cash benefits for at least 24 months, most persons with end-stage renal disease (ESRD), and certain otherwise noncovered aged persons who elect to pay a premium for Medicare coverage. Beginning in July 2001, persons with Amyotrophic Lateral Sclerosis (Lou Gehrig’s disease) are allowed to waive the 24-month waiting period. This

very broad description of Medicare eligibility is expanded in the next section. Medicare originally consisted of two parts:

- **Hospital Insurance (HI), or Part A:** Part A helps pay for inpatient hospital, home health agency, skilled nursing facility, and hospice care. Part A is provided free of premiums to most eligible people; certain otherwise ineligible people may voluntarily pay a monthly premium for coverage.
- **Supplementary Medical Insurance (SMI), or Part B:** Part B helps pay for physician, outpatient hospital, home health agency, and other services. To be covered by Part B, all eligible people must pay a monthly premium.
- **Medicare Advantage, or Part C:** This was established as the Medicare+Choice program by the Balanced Budget Act of 1997 (Public Law 105-33) and subsequently renamed and modified by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Public Law 108-173). The Medicare Advantage program expands beneficiaries' options for participation in private-sector health care plans.
- **Drug Coverage, Part D:** This plan helps pay for prescription drugs not otherwise covered by Part A or Part B. Part D initially provided access to prescription drug discount cards, on a voluntary basis and at limited cost to all enrollees (except those entitled to Medicaid drug coverage) and, for low-income beneficiaries, transitional limited financial assistance.

Entitlement and Coverage

Part A is generally provided automatically and free of premiums to persons aged 65 or older who are eligible for Social Security or Railroad Retirement benefits, whether they have claimed these monthly cash benefits or not. Also, workers and their spouses with a sufficient period of Medicare-only coverage in federal, state, or local government employment are eligible beginning at age 65. Similarly, individuals who have been entitled to Social Security or Railroad Retirement disability benefits for at least 24 months, and government employees with Medicare-only coverage who have been disabled for more than 29 months, are entitled to Part A benefits. (As noted previously, the waiting period is waived for persons with Lou Gehrig's disease. It should also be noted that, over the years, there have been certain liberalizations made to both the waiting period requirement and the limit on earnings allowed for entitlement to Medicare coverage based on disability.) Part A coverage is also provided to insured workers with ESRD (and to insured workers' spouses and children with ESRD), as well as to some otherwise ineligible aged and disabled beneficiaries who voluntarily pay a monthly premium for their coverage. In 2008, Part A provided protection against the costs of hospital and specific other medical care to about 45 million people (37.5 million aged and 7.4 million disabled enrollees). Part A benefit payments totaled \$232.3 billion in 2008.

Part A Coverages

The following health care services are covered under Part A:

- Inpatient hospital care. Coverage includes costs of a semiprivate room, meals, regular nursing services, operating and recovery rooms, intensive care, inpatient prescription drugs, laboratory tests, X-rays, psychiatric hospitals, inpatient rehabilitation, and long-term care hospitalization when medically necessary, as well as all other medically necessary services and supplies provided in the hospital. An initial deductible payment

is required of beneficiaries who are admitted to a hospital, plus copayments for all hospital days following day 60 within a benefit period (described later).

- Skilled nursing facility (SNF) care. Coverage is provided by Part A only if it follows within 30 days (generally) a hospitalization of 3 days or more and is certified as medically necessary. Covered services are similar to those for inpatient hospital care, and include rehabilitation services and appliances. The number of SNF days provided under Medicare is limited to 100 days per benefit period (described later), with a copayment required for days 21 through 100. Part A does not cover nursing facility care if the patient does not require skilled nursing or skilled rehabilitation services.
- Home health agency (HHA) care (covered by Parts A and B). The Balanced Budget Act transferred from Part A to Part B those home health services furnished on or after January 1, 1998, that are unassociated with a hospital or SNF stay. Part A will continue to cover the first 100 visits following a 3-day hospital stay or a SNF stay; Part B covers any visits thereafter. Home health care under Parts A and B has no copayment and no deductible. HHA care, including care provided by a home health aide, may be furnished part time by an HHA in the residence of a homebound beneficiary, if intermittent or part-time skilled nursing and/or certain other therapy or rehabilitation care is necessary. Certain medical supplies and durable medical equipment may also be provided, although beneficiaries must pay a 20 percent coinsurance for durable medical equipment, as required under Part B of Medicare. There must be a plan of treatment and periodic review by a physician. Full-time nursing care, food, blood, and drugs are not provided as HHA services.
- Hospice care. Coverage is provided for services to terminally ill persons with life expectancies of 6 months or less who elect to forgo the standard Medicare benefits for treatment of their illness and to receive only hospice care for it. Such care includes pain relief, supportive medical and social services, physical therapy, nursing services, and symptom management. However, if a hospice patient requires treatment for a condition that is not related to the terminal illness, Medicare will pay for all covered services necessary for that condition. The Medicare beneficiary pays no deductible for the hospice program but does pay small coinsurance amounts for drugs and inpatient respite care.

Benefit Period

An important Part A component is the benefit period, which starts when the beneficiary first enters a hospital and ends when there has been a break of at least 60 consecutive days since inpatient hospital or skilled nursing care was provided. There is no limit to the number of benefit periods covered by Part A during a beneficiary's lifetime; however, inpatient hospital care is normally limited to 90 days during a benefit period, and copayment requirements (detailed later) apply for days 61 through 90. If a beneficiary exhausts the 90 days of inpatient hospital care available in a benefit period, the beneficiary can elect to use days of Medicare coverage from a nonrenewable "lifetime reserve" of up to 60 (total) additional days of inpatient hospital care. Copayments are also required for such additional days.

Part B Coverages

All citizens (and certain legal aliens) aged 65 or older, and all disabled persons entitled to coverage under Part A, are eligible to enroll in Part B on a voluntary basis by payment of a monthly premium. Almost all persons entitled to Part A choose to enroll in

Part B. In 2016, Part B provided protection against the costs of physician and other medical services to about 55 million people (46 million aged and 9 million disabled enrollees). Part B benefits totaled \$167.8 billion in 2015.

Part B covers certain medical services and supplies, including the following:

- Physicians' and surgeons' services, including some covered services furnished by chiropractors, podiatrists, dentists, and optometrists;
- Services provided by Medicare-approved practitioners who are not physicians, including certified Registered nurse anesthetists, clinical psychologists, clinical social workers (other than in a hospital or SNF), physician assistants, and nurse practitioners and clinical nurse specialists in collaboration with a physician;
- Services in an emergency room, outpatient clinic, or ambulatory surgical center, including same-day surgery;
- Home health care not covered under Part A;
- Laboratory tests, X-rays, and other diagnostic radiology services;
- Certain preventive care services and screening tests;
- Most physical and occupational therapy and speech pathology services;
- Comprehensive outpatient rehabilitation facility services, and mental health care in a partial hospitalization psychiatric program, if a physician certifies that inpatient treatment would be required without it;
- Radiation therapy; renal (kidney) dialysis and transplants; heart, lung, heart-lung, liver, pancreas, and bone marrow transplants; and, as of April 2001, intestinal transplants;
- Approved durable medical equipment for home use, such as oxygen equipment and wheelchairs, prosthetic devices, and surgical dressings, splints, casts, and braces;
- Drugs and biologicals that are not usually self-administered, such as hepatitis B vaccines and immunosuppressive drugs (certain self-administered anticancer drugs are covered);
- Certain services specific to people with diabetes;
- Ambulance services, when other methods of transportation are contraindicated; and
- Rural health clinic and federally qualified health center services, including some telemedicine services.

To be covered, all services must be either medically necessary or one of several prescribed preventive benefits. Part B services are generally subject to a deductible and coinsurance (see next section). Certain medical services and related care are subject to special payment rules, including deductibles (for blood), maximum approved amounts (for Medicare-approved physical, speech, or occupational therapy services performed in settings other than hospitals), and higher cost-sharing requirements (such as those for certain outpatient hospital services). The preceding description of Part B-covered services should be used only as a general guide, due to the wide range of services covered under Part B and the quite specific rules and regulations that apply. Medicare Parts A and B, as described above, constitute the original fee-for-service Medicare program.

SMI Components

Since 2006, Part D has provided subsidized access to prescription drug insurance coverage on a voluntary basis for all beneficiaries upon payment of a premium, with premium and cost-sharing subsidies for low-income enrollees. Part D activities are

handled within the SMI trust fund but in an account separate from Part B. It should thus be noted that the traditional treatment of “SMI” and “Part B” as synonymous is no longer accurate, since SMI now consists of Parts B and D. The purpose of the two separate accounts within the SMI trust fund is to ensure that funds from one part are not used to finance the other. When Medicare began on July 1, 1966, approximately 19 million people enrolled. In 2016 there were 17.6 million beneficiaries enrolled in a Medicare Advantage plan (31% of the Medicare population).

Part C Benefits

Medicare Part C, also known as Medicare Advantage, is an alternative to traditional Medicare. Although all Medicare beneficiaries can receive their benefits through the traditional fee-for-service program, most beneficiaries enrolled in both Part A and Part B can choose to participate in a Medicare Advantage plan instead. Medicare Advantage plans are offered by private companies and organizations and are required to provide at least those services covered by Parts A and B, except hospice services. These plans may (and in certain situations must) provide extra benefits (such as vision or hearing) or reduce cost sharing or premiums.

The primary Medicare Advantage plans are:

- Local coordinated care plans, including health maintenance organizations (HMOs), provider-sponsored organizations, local preferred provider organizations (PPOs), and other certified coordinated care plans and entities that meet the standards set forth in the law. Generally, each plan has a network of participating providers. Enrollees may be required to use these providers or, alternatively, may be allowed to go outside the network but pay higher cost-sharing fees for doing so.
- Regional PPO plans, which began in 2006 and offer coverage to one of 26 defined regions. Like local PPOs, regional PPOs have networks of participating providers, and enrollees must use these providers or pay higher cost-sharing fees. However, regional PPOs are required to provide beneficiary financial protection in the form of limits on out-of-pocket cost sharing, and there are specific provisions to encourage regional PPO plans to participate in Medicare.
- Private fee-for-service plans, which for the most part do not have provider networks. Rather, members of a plan may go to any Medicare provider willing to accept the plan's payment.
- Special Needs Plans (SNPs), which are restricted to beneficiaries who are dually eligible for Medicare and Medicaid, live in long-term care institutions, or have certain severe and disabling conditions.

For individuals entitled to Part A or enrolled in Part B (except those entitled to Medicaid drug coverage), the new Part D initially provided access to prescription drug discount cards, at a cost of no more than \$30 annually, on a voluntary basis. For low-income beneficiaries, Part D initially provided transitional financial assistance (of up to \$600 per year) for purchasing prescription drugs, plus a subsidized enrollment fee for the discount cards. This temporary plan began in mid-2004 and phased out in 2006.

Part D Benefits

Since 2006, Part D provides subsidized access to prescription drug insurance coverage on a voluntary basis, upon payment of a premium, to individuals entitled to Part A or enrolled in Part B, with premium and cost-sharing subsidies for low-income enrollees. Beneficiaries may enroll in either a stand-alone prescription drug plan (PDP) or an integrated Medicare Advantage plan that offers Part D coverage. Enrollment began in late 2005. Part D provided protection against the costs of prescription drugs to about 46 million people in 2016. Part D coverage includes most FDA-approved prescription drugs and biologicals. (The specific drugs currently covered in Parts A and B remain covered there.)

Plans may set up formularies for their prescription drug coverage, subject to certain statutory standards. At its most basic level, a **formulary** is a list of medicines. Traditionally, a formulary contained a collection of formulas for the compounding and testing of medication (a resource closer to what would be referred to as a pharmacopoeia today). The main function of formularies today is to specify which medicines are approved to be prescribed under a particular contract. The development of formularies is based on evaluations of efficacy, safety, and cost-effectiveness of drugs.

Part D coverage can consist of either standard coverage or an alternative design that provides the same actuarial value. For an additional premium, plans may also offer supplemental coverage exceeding the value of basic coverage.

Not Covered

It should be noted that some health care services are not covered by any portion of Medicare. Noncovered services include long-term nursing care, custodial care, and certain other health care needs, such as dentures and dental care, eyeglasses, and hearing aids. These services are not a part of the Medicare program, unless they are a part of a private health plan under the Medicare Advantage program.

Program Financing, Beneficiary Liabilities, and Payments to Providers

All financial operations for Medicare are handled through two trust funds, one for Hospital Insurance (HI, Part A) and one for Supplementary Medical Insurance (SMI, Parts B and D). These trust funds, which are special accounts in the U.S. Treasury, are credited with all receipts and charged with all expenditures for benefits and administrative costs. The trust funds cannot be used for any other purpose. Assets not needed for the payment of costs are invested in special Treasury securities. The following sections describe Medicare's financing provisions, beneficiary cost-sharing requirements, and the basis for determining Medicare reimbursements to health care providers.

Program Financing

The HI trust fund is financed primarily through a mandatory payroll tax. Almost all employees and self-employed workers in the United States work in employment covered by Part A and pay taxes to support the cost of benefits for aged and disabled beneficiaries. The Part A tax rate is 1.45 percent of earnings, to be paid by each

employee and a matching amount by the employer for each employee, and 2.90 percent for self-employed persons. Beginning in 1994, this tax is paid on all covered wages and self-employment income without limit (Prior to 1994, the tax applied only up to a specified maximum amount of earnings). The Part A tax rate is specified in the Social Security Act and cannot be changed without legislation.

Part A also receives income from the following sources:

- (1) a portion of the income taxes levied on Social Security benefits paid to high-income beneficiaries,
- (2) premiums from certain persons who are not otherwise eligible and choose to enroll voluntarily,
- (3) reimbursements from the general fund of the U.S. Treasury for the cost of providing Part A coverage to certain aged persons who retired when Part A began and thus were unable to earn sufficient quarters of coverage (and those federal retirees similarly unable to earn sufficient quarters of Medicare-qualified federal employment),
- (4) interest earnings on its invested assets, and
- (5) other small miscellaneous income sources. The taxes paid each year are used mainly to pay benefits for current beneficiaries.

Trust Fund Differences

The SMI trust fund differs fundamentally from the HI trust fund with regard to the nature of its financing. As previously noted, SMI is now composed of two parts, Part B and Part D, each with its own separate account within the SMI trust fund. The nature of the financing for both parts of SMI is similar, in that both parts are primarily financed by contributions from the general fund of the U.S. Treasury and (to a much lesser degree) by beneficiary premiums.

For Part B, the contributions from the general fund of the U.S. Treasury are the largest source of income, since beneficiary premiums are generally set at a level that covers 25 percent of the average expenditures for aged beneficiaries. The standard Part B premium rate is \$134.00 per beneficiary per month in 2017. There are, however, three provisions that can alter the premium rate for certain enrollees (and the third reduced the premium for most enrollees in 2017). First, penalties for late enrollment (that is, enrollment after an individual's initial enrollment period) may apply, subject to certain statutory criteria. Second, beneficiaries whose income was above certain thresholds are required to pay an income-related monthly adjustment amount, in addition to their standard monthly premium. The 2017 Part B income-related monthly adjustment amounts and total monthly premium amounts to be paid by beneficiaries, according to income level and filing status, are shown in Table 1. Finally, a "hold-harmless" provision affects premiums.

Beneficiaries in Medicare Part D prescription drug coverage plans pay premiums that vary from plan to plan. Beginning in 2011, the Affordable Care Act required Part D beneficiaries whose modified adjusted gross income exceeds the same income thresholds that apply to Part B premiums to also pay a monthly adjustment amount. For 2017, the adjustment amount ranges are shown below.

Table 1 2017 Part B income-related monthly adjustment amounts

| Beneficiaries who file an individual tax return with income | Beneficiaries who file a joint tax return with income | Total monthly Part B premium amount |
|--|--|--|
| Less than or equal to \$85,000 | Less than or equal to \$170,000 | \$134.00 |
| Greater than \$85,000 and less than or equal to \$107,000 | Greater than \$170,000 and less than or equal to \$214,000 | \$187.50 |
| Greater than \$107,000 and less than or equal to \$160,000 | Greater than \$214,000 and less than or equal to \$320,000 | \$267.90 |
| Greater than \$160,000 and less than or equal to \$214,000 | Greater than \$320,000 and less than or equal to \$428,000 | \$348.30 |
| Greater than \$214,000 | Greater than \$428,000 | \$428.60 |

The monthly premium rates paid by beneficiaries who are married, but file a separate return from their spouses and who lived with their spouses at some time during the taxable year, are different. Those rates are as follows:

| Beneficiaries who are married, but file a separate tax return, with income: | Income-related monthly adjustment amount | Total monthly Part B premium amount |
|--|---|--|
| Less than or equal to \$85,000 | \$0.00 | \$134.00 |
| Greater than \$85,000 and less than or equal to \$129,000 | \$214.30 | \$348.30 |
| Greater than \$129,000 | \$294.60 | \$428.60 |

Hold-Harmless Provision

The “hold-harmless” provision, which prohibits increases in the standard Part B premium from exceeding the dollar amount of an individual’s Social Security cost-of-living adjustment, lowers the premium rate for most individuals who have their premiums deducted from their Social Security checks. The Social Security Administration announced that the cost-of-living adjustment (COLA) for Social Security benefits will be 0.3 percent for 2017. Because of the low Social Security COLA, a statutory “hold harmless” provision designed to protect seniors, will largely prevent Part B premiums from increasing for about 70 percent of beneficiaries. Among this group, the average 2017 premium will be about \$109.00, compared to \$104.90 for the past four years. For the remaining roughly 30 percent of beneficiaries, the standard monthly premium for Medicare Part B will be \$134.00 for 2017, a 10 percent increase from the 2016 premium of \$121.80. Because of the “hold harmless” provision covering the other 70 percent of beneficiaries, premiums for the remaining 30 percent must cover most of the increase in Medicare costs for 2017 for all beneficiaries. The Department of Health and Human Services (HHS) Secretary can mitigate projected premium increases for these beneficiaries, while continuing to maintain a prudent level of reserves to protect

against unexpected costs. The HHS will work with Congress as it explores budget-neutral solutions to challenges created by the “hold harmless” provision.

General Fund Contributions

For Part D, as with Part B, general fund contributions account for the largest source of income, since Part D beneficiary premiums are to represent, on average, 25.5 percent of the cost of standard coverage. The Part D base beneficiary premium for 2017 is \$35.63. The actual Part D premiums paid by individual beneficiaries equal the base beneficiary premium adjusted by a number of factors. In practice, premiums vary significantly from one Part D plan to another and seldom equal the base beneficiary premium. It is estimated that the average monthly premium for basic Part D coverage, which reflects the specific plan-by-plan premiums and the estimated number of beneficiaries in each plan, will be about \$34 in 2017. Penalties for late enrollment may apply. (Late enrollment penalties do not apply to enrollees who have maintained creditable prescription drug coverage.)

Beneficiaries meeting certain low-income and limited-resources requirements pay substantially reduced premiums or no premiums at all (and are not subject to late enrollment penalties) In addition to contributions from the general fund of the U.S. Treasury and beneficiary premiums, Part D also receives payments from the states. With the availability of prescription drug coverage and low-income subsidies under Part D, Medicaid is no longer the primary payer for prescription drugs for Medicaid beneficiaries who also have Medicare, and states are required to defray a portion of Part D expenditures for those beneficiaries. During the Part D transitional period that began in mid-2004 and phased out during 2006, the general fund of the U.S. Treasury financed the transitional assistance benefit for low-income beneficiaries. Funds were transferred to, and paid from, a Transitional Assistance account within the SMI trust fund.

The SMI trust fund also receives income from interest earnings on its invested assets, as well as a small amount of miscellaneous income. It is important to note that beneficiary premiums and general fund payments for Parts B and D are redetermined annually and separately. Payments to Medicare Advantage plans are financed from both the HI trust fund and the Part B account within the SMI trust fund in proportion to the relative weights of Part A and Part B benefits to the total benefits paid by the Medicare program.

Beneficiary Payment Liabilities

Fee-for-service beneficiaries are responsible for charges not covered by the Medicare program and for various cost-sharing aspects of Parts A and B. These liabilities may be paid;

- (1) by the Medicare beneficiary;
- (2) by a third party, such as an employer-sponsored retiree health plan or private Medigap insurance; or
- (3) by Medicaid, if the person is eligible.

Medigap

The term “Medigap” is used to mean private health insurance that pays, within limits, most of the health care service charges not covered by Parts A or B of Medicare. These policies, which must meet federally imposed standards, are offered by Blue Cross and Blue Shield and various commercial health insurance companies.

Beneficiary Payment Share

For beneficiaries enrolled in Medicare Advantage plans, the beneficiary’s payment share is based on the cost-sharing structure of the specific plan selected by the beneficiary, since each plan has its own requirements. Most plans have lower deductibles and coinsurance than are required of fee-for-service beneficiaries. Such beneficiaries, in general, pay the monthly Part B premium. However, some Medicare Advantage plans may pay part or all of the Part B premium for their enrollees as an added benefit. Depending on the plan, enrollees may also pay an additional premium for certain extra benefits provided (or, in a small number of cases, for certain Medicare-covered services).

For hospital care covered under Part A, a beneficiary’s fee-for-service payment share includes a one-time deductible amount at the beginning of each benefit period (\$1,316 in 2017). This deductible covers the beneficiary’s part of the first 60 days of each spell of inpatient hospital care. If continued inpatient care is needed beyond the 60 days, additional coinsurance payments (\$329 per day in 2017) are required through the 90th day of a benefit period. Each Part A beneficiary also has a “lifetime reserve” of 60 additional hospital days that may be used when the covered days within a benefit period have been exhausted. Lifetime reserve days may be used only once, and coinsurance payments (\$658 per day in 2017) are required. For skilled nursing care covered under Part A, Medicare fully covers the first 20 days of SNF care in a benefit period. But for days 21 through 100, a copayment (\$164.50 per day in 2017) is required from the beneficiary.

After 100 days per benefit period, Medicare pays nothing for SNF care. Home health care requires no deductible or coinsurance payment by the beneficiary. In any Part A service, the beneficiary is responsible for fees to cover the first 3 pints or units of nonreplaced blood per calendar year. The beneficiary has the option of paying the fee or of having the blood replaced. There are no premiums for most people covered by Part A. Eligibility is generally earned through the work experience of the beneficiary or of the beneficiary’s spouse. However, most aged people who are otherwise ineligible for premium-free Part A coverage can enroll voluntarily by paying a monthly premium, if they also enroll in Part B. For people with fewer than 30 quarters of coverage as defined by the Social Security Administration (SSA), the Part A monthly premium rate will be \$413 in 2017; for those with 30 to 39 quarters of coverage, the rate will be reduced to \$227. Penalties for late enrollment may apply. Voluntary coverage upon payment of the Part A premium, with or without enrolling in Part B, is also available to disabled individuals for whom coverage has ceased because earnings are in excess of those allowed.

For Part B, the beneficiary’s payment share includes the following:

- One annual deductible (\$183 in 2017), the monthly premiums,

- The coinsurance payments for Part B services (usually 20 percent of the remaining allowed charges with certain exceptions noted below),
- A deductible for blood,
- Certain charges above the Medicare-allowed charge (for claims not on assignment), and payment for any services not covered by Medicare.

For outpatient mental health services, the beneficiary is currently liable for 20 percent of the approved charges. This percentage phased down from 50 percent over the 5-year period 2010–2014. For services reimbursed under the outpatient hospital prospective payment system, coinsurance percentages vary by service and currently fall in the range of 20 percent to 50 percent. For certain services, such as clinical lab tests, HHA services, and some preventive care services, there are no deductibles or coinsurance.

Part D Payments

For the standard Part D benefit design, there is an initial deductible (\$400 in 2017). After meeting the deductible, the beneficiary pays 25 percent of the remaining costs, up to an initial coverage limit (\$3,700 in 2017). The beneficiary is then responsible for all costs until an out-of-pocket threshold is reached. (The 2017 out-of-pocket threshold is \$4,950) For costs thereafter, catastrophic coverage is provided, which requires enrollees to pay the greater of 5 percent coinsurance or a small defined copayment amount (\$3.30 in for generic or preferred multisource drugs and \$8.25 in 2017 for other drugs). The benefit parameters are indexed annually to the growth in average per capita Part D costs. Beneficiaries meeting certain low-income and limited-resources requirements pay substantially reduced cost-sharing amounts. In determining out-of-pocket costs, only those amounts actually paid by the enrollee or another individual (and not reimbursed through insurance) are counted; the exception to this “true out-of-pocket” provision is cost-sharing assistance from the low-income subsidies provided under Part D and from State Pharmacy Assistance programs. Many Part D plans offer alternative coverage that differs from the standard coverage. In fact, the majority of beneficiaries are not enrolled in the standard benefit design but rather in plans with low or no deductibles, flat payments for covered drugs, and, in some cases, partial coverage in the coverage gap. The monthly premiums required for Part D coverage are described in the previous section.

Payments to Providers

For Part A, before 1983, payments to providers were made on a reasonable cost basis. Medicare payments for most inpatient hospital services are now made under a reimbursement mechanism known as the prospective payment system (PPS). Under the PPS for acute inpatient hospitals, each stay is categorized into a diagnosis-related group (DRG). Each DRG has a specific predetermined amount associated with it, which serves as the basis for payment. A number of adjustments are applied to the DRG’s specific predetermined amount to calculate the payment for each stay. In some cases the payment the hospital receives is less than the hospital’s actual cost for providing Part A–covered inpatient hospital services for the stay; in other cases it is more. The hospital absorbs the loss or makes a profit. Certain payment adjustments exist for extraordinarily costly inpatient hospital stays and other situations. Payments for skilled nursing care, home health care, inpatient rehabilitation hospital care, long-term care

hospitals, inpatient psychiatric hospitals, and hospice are made under separate prospective payment systems.

For Part B, before 1992, physicians were paid on the basis of reasonable charge. This amount was initially defined as the lowest of;

- (1) the physician's actual charge,
- (2) the physician's customary charge, or
- (3) the prevailing charge for similar services in that locality.

Beginning January 1992, allowed charges are defined as the lesser of

- (1) the submitted charges or
- (2) the amount determined by a fee schedule based on a relative value scale (RVS). (In practice, most allowed charges are based on the fee schedule.)

Payments for durable medical equipment and clinical laboratory services are also based on a fee schedule. Most hospital outpatient services are reimbursed on a prospective payment system, and home health care is reimbursed under the same prospective payment system as Part A.

If a doctor or supplier agrees to accept the Medicare-approved rate as payment in full ("takes assignment"), then payments provided must be considered as payments in full for that service. The provider may not request any added payments (beyond the initial annual deductible and coinsurance) from the beneficiary or insurer. If the provider does not take assignment, the beneficiary will be charged for the excess (which may be paid by Medigap insurance). Limits now exist on the excess that doctors or suppliers can charge. Physicians are "participating physicians" if they agree before the beginning of the year to accept assignment for all Medicare services they furnish during the year. Since beneficiaries in the original Medicare fee-for-service program may select their doctors, they can choose participating physicians.

Medicare Advantage plans and their precursors have generally been paid on a capitation basis, meaning that a fixed, predetermined amount per month per member is paid to the plan, without regard to the actual number and nature of services used by the members. The specific mechanisms to determine the payment amounts have changed over the years. In 2006, Medicare began paying capitated payment rates to plans based on a competitive bidding process. For Part D, each month for each plan member, Medicare pays stand-alone PDPs and the prescription drug portions of Medicare Advantage plans their risk-adjusted bid (net of estimated reinsurance), minus the enrollee premium. Plans also receive payments representing premiums and cost-sharing amounts for certain low-income beneficiaries for whom these items are reduced or waived. Under the reinsurance provision, plans receive payments for 80 percent of costs in the catastrophic coverage category.

To help them gain experience with the Medicare population, Part D plans are protected by a system of "risk corridors" that allow Medicare to assist with unexpected costs and to share in unexpected savings. The risk corridors became less protective after 2007. Under Part D, Medicare provides certain subsidies to employer and union PDPs that continue to offer coverage to Medicare retirees and meet specific criteria in doing so.

Claims Processing

Medicare's Part A and Part B fee-for-service claims are processed by nongovernment organizations or agencies that contract to serve as the fiscal agent between providers and the federal government. These claims processors are known as intermediaries and carriers. They apply the Medicare coverage rules to determine the appropriateness of claims. Medicare intermediaries process Part A claims for institutional services, including inpatient hospital claims, SNFs, HHAs, and hospice services. They also process outpatient hospital claims for Part B. Examples of intermediaries are Blue Cross and Blue Shield (which utilize their plans in various states) and other commercial insurance companies. Intermediaries' responsibilities include:

- Determining costs and reimbursement amounts,
- Maintaining records,
- Establishing controls,
- Safeguarding against fraud and abuse or excess use,
- Conducting reviews and audits,
- Making the payments to providers for services, and
- Assisting both providers and beneficiaries as needed.

Medicare carriers handle Part B claims for services by physicians and medical suppliers. Examples of carriers are the Blue Shield plans in a state and various commercial insurance companies. Carriers' responsibilities include:

- Determining charges allowed by Medicare,
- Maintaining quality-of-performance records,
- Assisting in fraud and abuse investigations,
- Assisting both suppliers and beneficiaries as needed, and
- Making payments to physicians and suppliers for services that are covered under Part B.

Claims for services provided by Medicare Advantage plans (that is, claims under Part C) are processed by the plans themselves. Part D plans are responsible for processing their claims, akin to Part C. However, because of the "true out-of-pocket" provision discussed previously, the Centers for Medicare & Medicaid Services (CMS) has contracted the services of a facilitator, who works with CMS, Part D drug plans (stand-alone PDPs and the prescription drug portions of Medicare Advantage plans), and carriers of supplemental drug coverage to coordinate benefit payments and track the sources of cost-sharing payments. Claims under Part D also have to be submitted by the plans to CMS, so that certain payments based on actual experience (such as payments for low-income cost-sharing and premium subsidies, reinsurance, and risk corridors) can be determined.

Accurate Claims

Because of its size and complexity, Medicare is vulnerable to improper payments, ranging from inadvertent errors to outright fraud and abuse. Although providers are responsible for submitting accurate claims, and intermediaries and carriers are responsible for ensuring that only such claims are paid, there are additional groups whose duties include the prevention, reduction, and recovery of improper payments. Quality improvement organizations (QIOs, formerly called peer review organizations or PROs) are groups of practicing health care professionals who are paid by the federal

government to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. One function of QIOs is to ensure that Medicare pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting.

The ongoing effort to address improper payments intensified after enactment of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191), which created the Medicare Integrity Program (MIP). The MIP provides CMS with dedicated funds to identify and combat improper payments, including those caused by fraud and abuse, and, for the first time, allows CMS to award contracts competitively with entities other than carriers and intermediaries to conduct these activities. MIP funds are used for;

- (1) audits of cost reports, which are financial documents that hospitals and other institutions are required to submit annually to CMS;
- (2) medical reviews of claims to determine whether services provided are medically reasonable and necessary;
- (3) determinations of whether Medicare or other insurance sources have primary responsibility for payment;
- (4) identification and investigation of potential fraud cases; and
- (5) education to inform providers about appropriate billing procedures.

In addition to creating the MIP, HIPAA established a fund to provide resources for the Department of Justice- including the Federal Bureau of Investigation- and the Office of Inspector General (OIG) within the Department of Health and Human Services (HHS) to investigate and prosecute health care fraud and abuse. The Deficit Reduction Act (DRA) of 2005 (Public Law 109-171) established and funded the Medicare-Medicaid Data Match Program, which is designed to identify improper billing and utilization patterns by matching Medicare and Medicaid claims information. As is the case under the MIP, CMS can contract with third parties. The funds also can be used

- (1) to coordinate actions by CMS, the states, the Attorney General, and the HHS OIG to prevent improper Medicaid and Medicare expenditures and
- (2) to increase the effectiveness and efficiency of both Medicare and Medicaid through cost avoidance, savings, and the recoupment of fraudulent, wasteful, or abusive expenditures.

Administration

HHS has the overall responsibility for administration of the Medicare program. Within HHS, responsibility for administering Medicare rests with CMS. The Social Security Administration (SSA) assists, however, by initially determining an individual's Medicare entitlement, by withholding Part B premiums from the Social Security benefit checks of most beneficiaries, and by maintaining Medicare data on the Master Beneficiary Record, which is SSA's primary record of beneficiaries. The MMA requires SSA to undertake a number of additional Medicare-related responsibilities, including making low-income subsidy determinations under Part D, notifying individuals of the availability of Part D subsidies, withholding Part D premiums from monthly Social Security cash benefits for beneficiaries who request such an arrangement, and, for 2007 and later, determining the individual's Part B premium if the income-related monthly adjustment applies. The Internal Revenue Service (IRS) in the Department of the Treasury collects the Part A payroll taxes from workers and their employers. IRS data, in the form of

income tax returns, play a role in determining which Part D enrollees are eligible for low-income subsidies (and to what degree) and, for 2007 and later, which Part B enrollees are subject to the income-related monthly adjustment amount in their premiums (and to what degree).

A Board of Trustees, composed of two appointed members of the public and four members who serve by virtue of their positions in the federal government, oversees the financial operations of the HI and SMI trust funds. The Secretary of the Treasury is the managing trustee. Each year, around the first day of April, the Board of Trustees reports to Congress on the financial and actuarial status of the Medicare trust funds. State agencies (usually state health departments under agreements with CMS) identify, survey, and inspect provider and supplier facilities and institutions wishing to participate in the Medicare program. In consultation with CMS, these agencies then certify the facilities that are qualified.

Plan Information

- Medicare Advantage Plans
- Medicare Advantage Prescription Drug Plans, and
- Prescription Drug Plans (Medicare plans)

There is no single Medicare drug plan. To get coverage, you must enroll in a Medicare-approved private drug plan. There are at least two ways to get Medicare prescription drug coverage. You can join a **Medicare prescription drug plan** or you can join a Medicare Advantage plan (formerly called Medicare+Choice) with prescription drug coverage.

Medicare Advantage Plans

With the passage of the Balanced Budget Act of 1997, Medicare beneficiaries were given the option to receive their Medicare benefits through private health insurance plans, instead of through the original Medicare plan (Parts A and B). These programs were known as **Medicare+Choice** or **Part C** plans.

Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the compensation and business practices changed for insurers that offer these plans, and "Medicare+Choice" plans became known as **Medicare Advantage** (MA) plans.

Medicare has a standard benefit package that covers medically necessary care that beneficiaries can receive from nearly any hospital or (except in Alaska) doctor in the country. For people who choose to enroll in a Medicare private health plan, Medicare pays the private health plan a set amount every month for each member. Members may have to pay a monthly premium in addition to the Medicare Part B premium and generally pay a fixed amount (a copayment of \$20, for example) every time they see a doctor. The copayment can be higher to see a specialist.

The private plans are required to offer a benefit "package" that is at least as good as Medicare's and cover everything Medicare covers, but they do not have to cover every benefit in the same way. Plans that pay less than Medicare for some benefits, like skilled nursing facility care, can balance their benefits package by offering lower copayments for doctor visits. Private plans use some of the excess payments they

receive from the government for each enrollee to offer supplemental benefits. Some plans put a limit on their members' annual out-of-pocket spending on medical care, providing some insurance against catastrophic costs over \$5,000, for example. But many plans use the excess subsidies to offer dental coverage and other services not covered by Medicare and can leave members exposed to high medical bills if they fall seriously ill. Private plan members can end up with unexpectedly high out-of-pocket costs.

Almost all Medicare beneficiaries have access to at least two Medicare Advantage plans; most have access to three or more. The number of Medicare Advantage plans nationwide went from 2,014 in 2014 to 2,034 in 2017. According to research by the Kaiser Family Foundation, 17.6 million people (approximately 31% of all Medicare beneficiaries) were enrolled in Medicare Advantage plans in 2017, up from 10.5 million in March 2009. In their report, Kaiser noted that while most Medicare beneficiaries have dozens of private Medicare Advantage plans available in their community, enrollment is highly concentrated among a small number of firms in nearly all states.

Although the Patient Protection and Affordable Care Act of 2010 did not eliminate Medicare Advantage, it did eliminate subsidies which the federal government first used to establish the Medicare Advantage program and which many Medicare Advantage health insurance plans use to offer supplemental benefits. These subsidies (which added an additional \$14 billion to the Medicare program last year alone) will gradually be reduced until they are eliminated altogether.

Medicare Advantage Prescription Drug Plan

These private Medicare plans can provide coverage:

- A stand-alone **Prescription Drug Plan (PDP)**, which only covers the Medicare Part D prescription drugs, and not other medical costs.
- A **Medicare Advantage Prescription Drug Plan (MA-PD)** that provides all Medicare benefits in one plan, including prescription drugs. MA-PDs cover Medicare Parts A, B, and D. Only people with Medicare Parts A *and* B may enroll in a Medicare Advantage Plan.
- A **Medicare Advantage-Special Needs Plan (SNP)** that serves particular groups (such as people with specific diseases or conditions, people in nursing facilities, or people with Medicaid).

Both MA-PDs and SNPs can be coordinated care plans that offer the Medicaid benefits in coordination with all the client's Medicare benefits. Clients undergoing a continuing treatment of dialysis for End-Stage Renal Disease are not eligible for either of these plans. A client wishing to participate in these plans should choose both the Medicaid Managed Care plan and the Medicare Advantage plan offered by that company. Very few plans will allow an individual to remain in the Medicaid managed care plan if the client does not enroll in the Medicare plan offered by that company.

Unlike most of Medicare, private insurance plans offer prescription drug coverage. Plans choose drugs they will cover, their network pharmacies, and their monthly premiums. The plans must be approved by the Centers for Medicare and Medicaid Services (CMS) but each plan has flexibility in its design.

Each plan has a list of covered drugs called a formulary. The list must include both brand name and generic drugs. People should review the plan materials carefully to

make sure their drugs are covered and that their pharmacy is in the plan's pharmacy network.

Medicare Part D

This is a federal program to subsidize the costs of prescription drugs for Medicare beneficiaries. It was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and went into effect on January 1, 2006.

Program specifics

Eligibility and enrollment

Individuals are eligible for prescription drug coverage under a Part D plan if they are entitled to benefits under Medicare Part A and/or enrolled in Part B. Beneficiaries can obtain the Part D drug benefit through two types of private plans: they can join a Prescription Drug Plan (PDP) for drug coverage only or they can join a Medicare Advantage plan (MA) that covers both medical services and prescription drugs (MA-PD). The latter type of plan is actually part of Medicare Part C and has several other differences relative to original Medicare. About two-thirds of Part D beneficiaries are enrolled in a PDP option. Not all drugs will be covered at the same level, giving participants incentives to choose certain drugs over others. This is often implemented via a system of tiered formularies in which lower-cost drugs are assigned to lower tiers and thus are easier to prescribe or cheaper.

Dual eligibles (those also eligible for Medicaid benefits) were transferred from Medicaid prescription drug coverage to a Medicare Part D plan on January 1, 2006. They are automatically enrolled in one of the less expensive PDPs in their area, chosen at random. If the dual-eligible person is already enrolled in an MA-PD plan, then they are automatically removed from the MA plan upon enrollment in a PDP.

Most Medicare beneficiaries must affirmatively enroll in a Part D plan to participate. Annual enrollment periods last from November 15 to December 31 of the prior plan year. Starting in 2011 the enrollment period lasts from October 1 to December 7. Medicare beneficiaries who were eligible but did not enroll during the enrollment period must pay a late-enrollment penalty (LEP) to receive Part D benefits. This penalty is equal to 1% the national average premium times the number of years that they were eligible but not enrolled in Part D. The penalty raises the premium of Part D for beneficiaries, when and if they should elect coverage.

Part D enrollment for 2016 was 41 million beneficiaries. Participants choose a plan that best meets their individual needs. Plans are required to offer the "standard" benefit or one actuarially equivalent or they may offer more generous benefits. Medicare has made available an interactive online tool called the **Medicare Plan Finder** that allows for comparison of coverage and costs for all plans in a geographic area. The tool allows one to enter a list of medications along with pharmacy preferences. It can show the beneficiary's total annual costs for each plan along with a detailed breakdown of the plans' monthly premiums, deductibles, and prices for each drug during each phase of the benefit design. Plans are required to update this site with current prices and formulary information every other week throughout the year.

Costs to beneficiaries

Beneficiary cost sharing (deductibles, coinsurance, etc.)

The CMS establishes a standard drug benefit that Part D plans must offer. The standard benefit is defined in terms of the benefit structure and not in terms of the drugs that must be covered. In 2017, the standard benefit requires payment of a \$400 deductible, then 25% coinsurance drug costs up to an initial coverage limit of \$3,700. Once this initial coverage limit is reached, the beneficiary must pay the full cost of his/her prescription drugs up until the total out-of-pocket expenses reach \$4,950 (excluding premiums). This coverage gap existing between the initial coverage limit and the catastrophic coverage limit is referred to more commonly as the "Donut Hole". Once the beneficiary reaches catastrophic coverage, he or she pays the greater of 5% coinsurance, or \$3.30 for generic drugs and \$8.25 for brand-named drugs. The catastrophic coverage amount is calculated on a yearly basis, and a beneficiary who reaches catastrophic coverage by December 31 of one year will start his or her deductible anew on January 1.

The standard benefit is not the most common benefit offered by Part D plans. Only 11 percent of PDPs for 2017 offer the defined standard benefit. Plans vary widely in their formularies and cost-sharing requirements. Most eliminate the deductible and use tiered drug co-payments rather than coinsurance. The only out-of-pocket costs that count toward getting out of the coverage gap and into catastrophic coverage are True Out-Of-Pocket (TrOOP) expenditures. TrOOP expenditures accrue only when drugs on plan's formulary are purchased in accordance with the restrictions on those drugs. Monthly premium payments do not count towards TrOOP.

Under The Patient Protection and Affordable Care Act of 2010, the "Donut Hole" coverage gap will be gradually eliminated through a combination of measures including brand-name prescription drug discounts, generic drug discounts, and a gradual decrease in the "catastrophic coverage" threshold. The "Donut Hole" coverage gap is due to be completely eliminated by 2020. Most plans use specialty drug tiers, and some have a separate benefit tier for injectable drugs. Beneficiary cost sharing can be higher for drugs in these tiers.

Beneficiary premiums

The average (weighted) monthly premium for PDPs are projected to increase to \$42.17 for 2017. This estimate includes premiums for both basic and enhanced PDPs, assumes current PDP enrollees remain in their same plan, and does not make assumptions about plan choices by new enrollees for 2017. PDP premiums will continue to vary widely across plans in 2017, as in previous years.

Low-Income Subsidies

Medicare offers several Medicare Savings Programs (MSPs) that assist people with low income and assets: Qualified Medicare Beneficiary (QMB), Specified Low-Income Medicare Beneficiary (SLMB), Qualified Individual (QI) and Qualified Disabled Working Individual (QDWI). Certain income and asset limits must be met to qualify for these programs, which are administered by the state Medicaid program.

Qualified Medicare Beneficiaries- A QMB is an aged or disabled Medicare beneficiary who has:

- (1) income at or below the Federal poverty line; and
- (2) resources below 200 percent of the resources limit set for the Supplemental Security Income (SSI) Program (the QMB resources limits for 2017 are \$7,390 for an individual and \$11,090 for a couple). An individual's home and household goods are excluded as resources. To meet the QMB definition, the person must be entitled to Medicare Part A.

Specified low-income Medicare beneficiaries (SLMBs)- Medicaid will pay partial or full Medicare Part B premiums for eligible SLMBs. Individual monthly income limit, \$1,226; Married couple monthly income limit, \$1,644; Individual resource limit, \$7,390; Married couple resource limit, \$11,090. These are persons meeting the QMB criteria except that their income is slightly over the QMB limit. The SLMB income limit is 120 percent of the Federal poverty line. SLMB is limited to payment of the Medicare Part B premiums, unless the beneficiary is otherwise eligible for Medicaid.

Qualifying individuals (QI-s)- The Balanced Budget Act of 1997 required State Medicaid Programs, effective January 1, 1998 through December 31, 2002, to pay Part B premiums for beneficiaries with incomes up to 135 percent of poverty. These persons are referred to as QI-1s. QI benefits must be applied for every year. QI applications are granted on a first-come, first-served basis, with priority given to people who got QI benefits the previous year. (You cannot get QI benefits if you qualify for Medicaid). QI income & resource limits in 2017: Individual monthly income limit, \$1,377; Married couple monthly income limit \$1,847; Individual resource limit, \$7,390; Married couple resource limit, \$11,090. The program helps pay for Part B premium only.

Qualified disabled and working individuals (QDWIs)- Medicaid is authorized to provide partial protection against Medicare Part A premiums for QDWIs. QDWIs are persons who were previously entitled to Medicare on the basis of a disability, who lost their entitlement based on earnings from work, but who continue to have the disabling condition. Medicaid is required to pay the Medicare Part A premium for such persons if their incomes are below 200 percent of the Federal poverty line, their resources are below 200 percent of the SSI limit, and they are not otherwise eligible for Medicaid. QDWI income & resource limits in 2017: Individual monthly income limit, \$4,045; Married couple monthly income limit, \$5,425; Individual resource limit, \$4,000; Married couple resource limit, \$6,000. Program helps pay for Part A premiums only

Low-income Drug Subsidies

One option for those struggling with drug costs is the low-income subsidy. Beneficiaries with income below 150% poverty are eligible for the low-income subsidy, which helps pay for all or part of the monthly premium, annual deductible, and drug co-payments.

Excluded drugs

While CMS does not have an established formulary, Part D drug coverage excludes drugs not approved by the Food and Drug Administration, those prescribed for off-label use, drugs not available by prescription for purchase in the United States, and drugs for which payments would be available under Parts A or B of Medicare. Part D coverage

excludes drugs or classes of drugs which may be excluded from Medicaid coverage.

These may include:

- Drugs used for anorexia, weight loss, or weight gain
- Drugs used to promote fertility
- Drugs used for erectile dysfunction
- Drugs used for cosmetic purposes (hair growth, etc.)
- Drugs used for the symptomatic relief of cough and colds
- Barbiturates
- Benzodiazepines
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
- Drugs where the manufacturer requires as a condition of sale any associated tests or monitoring services to be purchased exclusively from that manufacturer or its designee

While these drugs are excluded from basic Part D coverage, drug plans can include them as a supplemental benefit, provided they otherwise meet the definition of a Part D drug. However plans that cover excluded drugs are not allowed to pass on those costs to Medicare, and plans are required to repay CMS if they are found to have billed Medicare in these cases.

Plan formularies

Part D plans are not required to pay for all covered Part D drugs. They establish their own formularies, or list of covered drugs for which they will make payment, as long as the formulary and benefit structure are not found by CMS to discourage enrollment by certain Medicare beneficiaries. Part D plans that follow the formulary classes and categories established by the United States Pharmacopoeia will pass the first discrimination test. Plans can change the drugs on their formulary during the course of the year with 60 days notice to affected parties.

Typically, each Plan's formulary is organized into tiers, and each tier is associated with a set copay amount. Most formularies have between 3 and 5 tiers; the lower the tier, the lower the copay amount. For example, Tier 1 might include all of the Plan's preferred generic drugs, and each drug within this tier might have a copay of \$5–10 per prescription. Tier 2 might include the Plan's preferred brand drugs with a copay of \$20–\$30, while Tier 3 may be reserved for non-preferred brand drugs which are covered by the plan at a higher copay level - perhaps \$40–\$100. Tiers 4 and higher typically contain specialty drugs, which have the highest copays because they are generally quite expensive.

The Plan's tiered copay amounts for each drug only apply during the initial period before the coverage gap. Once in the coverage gap, also known as the Donut Hole, the person must pay for 100% of the prescription costs, based on prices established by the Plan. In 2008, 4% of Medicare beneficiaries spent enough to qualify for catastrophic coverage at which point the beneficiary pays 5% of the total drug cost or a co-payment of \$2 for generics/preferred drugs and \$5 for brand-name drugs, whichever is greater. In 2009, Plans reach catastrophic coverage when the beneficiary reaches \$6,154 in total drug costs.

The primary differences between the formularies of different Part D plans relate to the coverage of brand-name drugs. Nine out of the ten plans with the highest enrollment increased the number of drugs on their formularies in 2007. Plans have generally made fewer changes for 2008.

Number of participants

At the start of the program in January 2006, it was expected that eleven million people would be covered by Medicare Part D; of those, six million would be dual eligible. About two million people who were covered by employers would likely lose their employee benefits.

As of January 30, 2007, nearly 24 million individuals were receiving prescription drug coverage through Medicare Part D (PDPs and MA-PDs combined), according to CMS.

Medicare Part D Coverage Gap

The **Medicare Part D coverage gap**- informally known as the **Medicare donut hole**- is the difference of the initial coverage limit and the catastrophic coverage threshold, as described in the Medicare Part D prescription drug program administered by the United States federal government. After a Medicare beneficiary surpasses the prescription drug coverage limit, the Medicare beneficiary is financially responsible for the entire cost of prescription drugs until the expense reaches the catastrophic coverage threshold.

Details

Most Medicare Prescription Drug Plans have a coverage gap. This means there is a temporary limit on what the drug plan will cover for drugs. Not everyone will enter the coverage gap. The coverage gap begins after an individual has spent a certain amount for covered drugs. In 2017 the gap begins at \$3,700. This amount may change each year.

Brand-name prescription drugs

Once the coverage gap is reached an enrollee will pay no more than 40% of the plan's cost for covered brand-name prescription drugs. Some plans may offer higher savings in the coverage gap. The discount will come off of the price that a plan has set with the pharmacy for a specific drug.

Although an individual will pay no more than 40% of the price for the brand-name drug in 2017, 95% of the price (what gets paid plus the 50% manufacturer discount payment) will count as out-of-pocket costs which will help get out of the coverage gap. These items are not counted toward the out-of-pocket spending:

- What the drug plan pays toward the drug cost (5% of the price)
- What the drug plan pays toward the dispensing fee (55% of the fee)

Example

Mrs. Anderson reaches the coverage gap in her Medicare drug plan. She goes to her pharmacy to fill a prescription for a covered brand-name drug. The price for the drug is \$60, and there's a \$2 dispensing fee that gets added to the cost. Mrs. Anderson pays 40% of the plan's cost for the drug and dispensing fee ($\$62 \times .40 = \24.80). The amount

Mrs. Anderson pays (\$24.80) plus the manufacturer discount payment (\$30.00) count as out-of-pocket spending. So, \$54.80 counts as out-of-pocket spending and helps Mrs. Anderson get out of the coverage gap. The remaining \$7.20, which is 10% of the drug cost and 60% of the dispensing fee paid by the drug plan, does not count toward Mrs. Anderson's out-of-pocket spending.

If a plan participant has a Medicare drug plan that already includes coverage in the gap, he or she may get a discount after your plan's coverage has been applied to the drug's price. The discount for brand-name drugs will apply to the remaining amount that the individual owes.

Generic drugs

In 2017, Medicare will pay 49% of the price for generic drugs during the coverage gap. The plan participant will pay the remaining 51% of the price. What an individual pays for generic drugs during the coverage gap will decrease each year until it reaches 25% in 2020. The coverage for generic drugs works differently from the discount for brand-name drugs. For generic drugs, only the amount paid will count toward getting out of the coverage gap.

Example

Mr. Evans reaches the coverage gap in his Medicare drug plan. He goes to his pharmacy to fill a prescription for a covered generic drug. The price for the drug is \$20, and there's a \$2 dispensing fee that gets added to the cost. Mr. Evans will pay 51% of the plan's cost for the drug and dispensing fee ($\$22 \times .51 = \11.22). The \$11.22 he pays will be counted as out-of-pocket spending to help him get out of the coverage gap. If you have a Medicare drug plan that already includes coverage in the gap, you may get a discount after your plan's coverage has been applied to the drug's price.

Items that count towards the coverage gap

- Your yearly deductible, coinsurance, and copayments
- The discount you get on brand-name drugs in the coverage gap
- What you pay in the coverage gap

Items that do not count towards the coverage gap

- The drug plan premium
- Pharmacy dispensing fee
- What you pay for drugs that aren't covered

Medicare Prescription Drug Plans (Medicare plans)

A stand-alone drug plan, offered by insurers and other private companies to beneficiaries that receive their Medicare Part A and/or B benefits through Original Medicare; Medicare Private Fee-for-Service Plans that don't offer prescription drug coverage; and Medicare Cost Plans offering Medicare prescription drug coverage.

Medigap

Medigap (Medicare Supplement) refers to various private supplemental health insurance plans sold to Medicare beneficiaries in the United States that provide coverage for medical expenses not or only partially covered by Medicare. Medigap's

name is derived from the notion that it exists to cover the difference or "gap" between the expenses reimbursed by Medicare and the total amount charged.

Eligibility

A person must be enrolled in part A and B of Medicare before they can enroll in a Medigap plan. During the open enrollment period which begins within 6 months of turning 65 or enrolling in Medicare Part B at 65 or older, a person may obtain a Medigap plan on a guaranteed issue basis (i.e. no medical screening required). Outside of open enrollment, the issuing insurance company may require medical screening and may obtain an attending physician's statement if necessary. Medigap insurance is not compatible with other forms of private Medicare coverage, such as a Medicare Advantage plan.

Products available

Medigap offerings have been standardized by the CMS into twelve different plans, labeled A through L, sold and administered by private companies. Each Medigap plan offers a different combination of benefits. The coverage provided is roughly proportional to the premium paid. However, many older Medigap plans offering minimal benefits will cost more than current plans offering full benefits. The reason behind this is that older plans have an older average age per person enrolled in the plan, causing more claims within the group and raising the premium for all members within the group. Since Medigap is private insurance and not government sponsored, the rules governing the sale and offerings of a Medigap insurance policy can vary from state to state. Some states such as Massachusetts, Minnesota, and Wisconsin require Medigap insurance to provide additional coverage than what is defined in the standardized Medigap plans. Some employers may provide Medigap coverage as a benefit to their retirees. While Medigap offerings have been standardized since 1992, some seniors who had Medigap plans prior to 1992 are still on non-standard plans. Those plans are no longer eligible for new policies.

Drug coverage

Some Medigap policies sold before January 1, 2006 may include prescription drug coverage, but after that date no new Medigap policies could be sold with drug coverage. This time frame coincides with the introduction of the Medicare Part D benefit. Medicare beneficiaries who enroll in a stand alone Part D plan may not retain the drug coverage portion of their Medigap policy. People with Medigap policies that include drug coverage who enrolled in Medicare Part D by May 15, 2006 had a guaranteed right to switch to another Medigap policy that has no prescription drug coverage. Beneficiaries choosing to retain a Medigap policy with drug coverage after that date have no such right; in that case the opportunity to switch to a Medigap policy without drug coverage is solely at the discretion of the private insurance company issuing the replacement policy, but the beneficiary may choose to remove drug coverage from their current Medigap policy and retain all other benefits.

Product Suitability

Many companies maintain a requirement to do a suitability explanation to substantiate the sale. The agent's goal is to help provide clients with the best possible outcomes when dealing with insurance carriers and to also help the agent with business submitted. Getting it right the first time without experiencing any delays is in everyone's best interest. The main purpose of **suitability standards** is to make clear that life and health insurers cannot classify individuals without a rational basis for each decision.

In theory it would seem reasonable for beneficiaries to hear about all their Medicare-related choices during a single presentation. The reality of markets is different; Insurers may incentivize producers to push one product over another without regard to suitability. Meanwhile, it is not reasonable to believe that consumers will be able to absorb details and nuances about the broad spectrum of Medicare-related products. Limiting a presentation could be seen as desirable under certain circumstances. Beneficiaries are not limited in the information available to them, as they may make a later appointment to discuss other products. In order to learn about their range of choices, beneficiaries may seek information from State Health Insurance and Assistance Programs (SHIP) counselors or other neutral parties to determine the most suitable type(s) of product before requesting sales appointments.

Self-regulatory rulemaking should thoroughly explain the need for new rules, practices, or interpretations supported by quantifiable rationale. Burdens of new regulations must be carefully balanced against the regulatory goals of each proposal. Every self-regulatory initiative should be meaningful to insurers as well as to producers. These essential approaches to rulemaking ensure that new rules and responsive enterprise-wide compliance procedures are appropriate. Suitability rulemaking demands careful scrutiny and compelling justification. The proposal voices concern over increased patterns of unsuitable Medicare-related product sales. The assertion is that "some prospective purchasers continue to be confused by certain features" of Medicare-related products.

Making certain Medicare-related products are suitable for the end user is imperative and this is something that insurance firms might help agents to achieve. Suitability factors are clearly one of the key considerations of the governing bodies that regulate the insurance industry. Making sure that the end user will benefit from a Medicare-related product is an absolute must. Understanding the complexities of the healthcare industry with regards to issues of suitability and product fit is invariably a hardship on agents and that is why most those operating successfully today will realize that they simply could not promote products for seniors efficiently without the help of suitability evaluations.

Compliance System

Each insurer is obligated to operate a system that is reasonably designed to achieve the compliance regulatory goal; that is to supervise recommendations. An insurer may comply by establishing and maintaining the insurer's own compliance system. Each agent and independent agency should adopt an insurer's compliance system or establish and maintain a functional system of its own. A compliance system should include:

- maintenance of written procedures
- periodic reviews of the insurer's or agent's records in a manner reasonably designed to assist in detecting and preventing sales abuses

Agent or insurers need to adopt procedures for conducting compliance reviews that are reasonable under the circumstances. An insurer that contracts with a third party and that complies with the requirements to supervise is deemed to have complied with the insurer's responsibilities.

Recording Client Needs

Each agent, independent agency, and insurer should maintain, or otherwise be able to account for, records of the information collected from the consumer and other information used in making a recommendation that was the basis for a transaction for a reasonable period of time. An insurer may, but is not required to, maintain documentation on behalf of an agent.

It is also important that agents identify and thoughtfully evaluate the needs of their clients. This can be achieved with a thorough examination of the client's goals, objectives, and expectations. Some of the more common considerations in this investigation are:

- The client's perspective of his or her objectives and whether they are achievable
- The client's time table for achieving his/her objectives
- Current and projected interest rates
- Inflation assumptions

The duty of good faith and fair dealing requires an agent to sell only appropriate products to his clients. For example, he must sell the right amount of insurance for the right reasons. Accurate and reliable recommendations for purchasing a product must be made based upon the appropriateness of the product for meeting the needs of the client and not some personal objectives of the agent.

Suitability requirements also should entail explaining and reviewing a personal worksheet with applicants. Here is an example.

Example 10-Step Medicare Suitability Audit

1. Basic Information

First Name _____ Last _____

Street _____ City _____

Zip Code _____ County _____

Date of Birth: _____

2. Qualifying Information

| | | |
|--|-----|----|
| Do you have Medicare Part A? | Yes | No |
| Do you have Medicare Part B? | Yes | No |
| If not, have you applied for Medicare? | Yes | No |

3. Medical Information (For Product Suitability Only)

Who is your Primary Care Physician? _____

Which hospital system do you prefer? _____

4. Prescription Drug Information (For Product Suitability Only)

What prescription medications are you currently taking?

What is your current monthly out of pocket expense for your medications?

5. Plan Information

What is your current insurance plan? _____

What do you like most about this plan? _____

What do you dislike most about this plan? _____

6. Plan Preferences

On a scale of 1 –10 please Rate the Following Preferences

| | |
|--|----------------------|
| Keeping the Same Primary Care Physician I have now | 1-2-3-4-5-6-7-8-9-10 |
| Freedom to See Any Doctor or Hospital I Choose | 1-2-3-4-5-6-7-8-9-10 |
| Being Able to Predict My Expenses | 1-2-3-4-5-6-7-8-9-10 |

7. Extra Help Qualification

Did you get a letter from Medicare or the Social Security Administration (SSA) that said you are either eligible for or qualified for extra help paying for your Medicare

Prescription drug plan costs? Yes No

8. Extra Help Needs

Do you feel like you need extra help paying for your Health Coverage or Prescription Drugs? Yes No

If yes, what is your current total household income? _____

If yes, what is the current value of all of your savings and investments?

9. What is your greatest concern about your health coverage in the future?

10. What is the most important quality you seek in a health insurance agent?



Prohibited Sales Practices

While most insurance agents who sell Medicare Advantage plans match their clients with suitable plans, some agents have used questionable sales tactics to sell products. Such documented cases include:

- Removing beneficiaries from traditional Medicare without their knowledge
- Enrolling beneficiaries in plans they can't afford
- Misleading enrollees to believe their physician or hospital accepts their plan

Complaints about inappropriate or confusing marketing and sales practices leading seniors to enroll in a MA plan without adequately understanding their choice, or even knowing that they had been moved out of traditional Medicare. There are complaints about cross-selling, where insurance agents and brokers use Medicare Part D as a pretext to simply get in the door with a senior, a situation not prohibited by Medicare marketing guidelines. Once inside, agents instead sell the senior an unrelated and sometimes unsuitable insurance product.

What Agents CAN Do

When marketing Medicare products, agents can:

- Distribute information and forms in a retail setting or while participating at a health fair or promotional event.
- Travel to meet Medicare beneficiaries in their home- provided they have been invited.
- Provide consumers information about public assistance programs and help individuals apply for government subsidies.
- Call potential enrollees- as long as they follow federal and state calling hours and the FTC Telemarketing Sales Rules/National Do-Not-Call Registry.

What Agents CANNOT Do

When marketing Medicare products, agents cannot:

- Engage in high-pressure sales tactics.
- Solicit Medicare beneficiaries door-to-door.
- Send unsolicited e-mails.
- Collect names, addresses and enrollment applications or conduct sales presentations at health fairs, educational or promotional events.
- Sell products which are not health-related during a Medicare Advantage or prescription drug plan sales or marketing presentation.
- Provide meals at promotional and sales events.
- Sell products in health care settings (doctor's offices, pharmacies, etc.).
- Make misrepresentations or omit information about a comparative Medicare product to induce a person to buy or change their insurance.
- Use fraudulent or dishonest practices.

The Public Can Avoid Becoming Victims of Predatory Sales Tactics

Agents can disseminate the following common-sense warnings to prospective plan purchasers as a service. The agent who helps clients helps himself

- Be wary of individuals who claim they work for Medicare. Medicare representatives do not make house calls or solicit beneficiaries by telephone.
- Be cautious of individuals selling Medicare products door-to-door. If someone comes to your home without a scheduled appointment, do not let the individual in your home or provide him or her with personal information.
- Beware of insurance agents who tell you it is free to enroll in a Medicare program. Premiums are associated with all Medicare products.
- Be leery of insurance agents who tell you your enrollment in a Medicare Advantage Plan will not affect your Medicare coverage. When you sign up for a Medicare Advantage Plan you will be removed from your traditional Medicare plan and may incur more expenses in terms of deductibles and co-payments.
- Do not be persuaded by an insurance agent who tries to scare you into believing your Medicare rates are going to increase if you do not switch plans immediately.

Complying With the Medicare Marketing Guidelines

During the open enrollment period, departments of insurance want to ensure Medicare beneficiaries are not pressured into choosing a Medicare plan. The Department further hopes all agents selling Medicare products provide consumers with a detailed and thorough overview of the products they are marketing so consumers are able to select a plan that best fits their needs.

All agents marketing Prescription Drug (PDP) and Medicare Advantage (MA) plans are to abide by the CMS guidelines established as well as all applicable state laws. In light of the above, all insurers and agents are encouraged to review the CMS Guidelines and the following state statutes generally:

- The Deceptive Trade Practices Act (DTPA) – Sections of the Business and Commerce Code,
- The use or employment by any person of an act or practice in violation of the article of the insurance code- cause of action for unfair or deceptive insurance practices.

Unfair & Deceptive Sales Practices Defined

Unfair Method of Competition, Sanctions and Penalties

Failure of an insurer or agent to comply with the appropriate rules and regulations only invites trouble. Here are some of the activities that are considered unacceptable;

- deceptive or misleading information set forth in any sales material;
- failing to ask the applicant in completing the application the pertinent questions regarding the possibility of financing or replacement;
- intentionally recording an answer incorrectly;
- advising an applicant to respond negatively to any question regarding replacement in order to prevent notice to the existing insurer
- advising a policy or contract owner to contact the insurer directly in such a way as to attempt to obscure the identity of the replacing agent or insurer.

A policy or contract owner has the right to replace an existing life insurance policy or annuity contract after indicating in or as a part of applications for new coverage that replacement is not the intention. However, patterns of that action by policy or contract owners of the same agent is be deemed prima facie evidence of the agent's knowledge that replacement was intended in connection with the identified transactions, and those patterns of action will be deemed prima facie evidence of the agent's intent to violate the rules. If it is determined that the requirements discussed here have not been met, the replacing insurer is to provide the policy owner an in force illustration. If an in force illustration is not available, a policy summary for the replacement policy or an available disclosure document for the replacement contract; and the appropriate notice regarding replacements.

Additional Sanctions

An insurer or agent that violates these regulations is subject to sanctions which may include:

- the revocation or suspension of the agent's license or the insurer's certificate of authority
- administrative penalties
- forfeiture of any commissions or other compensation paid to an agent as a result of the transaction in connection with which the violations occurred.

If it is determined that the violations of this chapter were material to the sale, the insurer may be required to make restitution, restore policy or contract values; and pay interest at the rate set by Sec 84.050 on the amount refunded in cash.

Advertising Prohibitions

The words "savings," "investment," "deposit," "investment plan" and similar terms cannot be used to refer to the premium or to the interest to be credited to the contract in a context or under such circumstances or conditions that have the capacity or tendency to confuse or mislead the proposed purchaser as to the nature and limitations of the product or to any benefits received from it.

- An advertisement must not use the phrase "low cost" or "low cost plan" without providing a demonstration that a composite of lower production, administrative, and claim cost resulting in a low premium rate to the public.
- An advertisement may not imply that there are advantages that usually apply to group coverage, and/or uses words such as certificate or enrollment, when the policy offered is actually an individual policy. (There are some individual policies that have discounted rates for minimum levels of participation; ads for such policies may describe those discounts.) Neither may an advertisement imply that prospective policyholders would become part of a group or other relationship that does not, in fact, exist.
- An advertisement for life, accident and health, or annuities may not use the existence of the Guaranty Association (fund) as an inducement to purchase coverage.

Not Considered Advertising

The following materials are not considered to be advertising provided they are not used to urge the purchase, increase, modification, or retention of a policy of insurance:

- Materials used by an insurance company within its own organization and not for public distribution;
- Communications with policyholders;
- A general announcement sent by a group policyholder to members of the eligible group that a policy has been written or arranged; or
- Correspondence between a prospective group policyholder and an insurer in the course of negotiating a group contract.
- Agent recruitment/training materials, i.e., materials used solely for the training, recruitment, and education of an insurer's personnel, and agents. Statements in such materials that are intended to be used, or that *may* be used, in consumer sales presentations are *not* exempt. We do not assume that *all* agent training material is exempt.

Note: The company may not misrepresent products to its own agents.

[...But the wisdom and authority of the legislator are seldom victorious in a contest with the vigilant dexterity of private interest

History of the Decline and Fall of the Roman Empire, E Gibbon, 1782]

Marketing Misconduct

The following is adapted from Congressional testimony

U.S. House of Representatives

Committee on Energy & Commerce

Hearing by the Subcommittee on Oversight & Investigations

June 26, 2007

Written Testimony of California Health Advocates

The introduction of the Part D prescription drug benefit coupled with the dramatic growth in the types and numbers of Medicare Advantage plans being sold across the country have increased both the complexity of and confusion surrounding the Medicare program, leading to an environment that is ripe for abuse. The current landscape and choices facing Medicare beneficiaries, examples of how agents have exploited these choices, and the difficulty of undoing the damage of bad choices due to marketing misconduct are discussed below.

Medicare Landscape

The Medicare Modernization Act injected new incentives for private companies to offer a range of new products to Medicare beneficiaries, greatly increasing the number and types of plans available, all of which have significant flexibility to design their benefits and cost-sharing structures. When choosing how to obtain coverage through Medicare, an individual has a range of variables s/he must consider, based upon any current coverage s/he might have. As consumers struggle to find the best combination of prescription drug and medical benefits for their individual needs, they must navigate a dizzying array of configurations and cost-sharing arrangements available through Original Medicare, Medicare supplemental insurance plans (Medigap), Medicare Advantage (MA) plans, and retiree or other coverage. There are multiple variations between and among these different options. Some individuals are eligible for both Medicare and Medicaid, or some other program that can help pay for some or all of their costs.

Within the Medicare Advantage program there are multiple plan designs, including: Health Maintenance Organizations (HMOs); Preferred Provider Organizations (PPOs); Special Needs Plans (SNPs); Private Fee-for-Service (PFFS) plans; and Medical Savings Accounts (MSAs). Some MA plans offer Medicare Part D prescription drug coverage, others don't. Depending upon what type of MA plan an individual is enrolled in, s/he may have a right to obtain separate prescription drug coverage outside of their MA plan. Depending upon where an individual Medicare beneficiary lives, there may be an overwhelming number of private plan options available to him or her. (E.g., by the count of the organization giving testimony, there were 106 plan options available in Los Angeles County in 2007: 55 stand-alone prescription drug plans (PDPs), available statewide; 36 "health plans" (including 2 regional PPOs, 1 local PPO, 26 local HMOs [2 of which are only available in parts of the county], 6 PFFS plans and 1 MSA); and 15 Special Needs Plans (SNPs). See www.medicare.gov.

Some of these combinations of Medicare, private and employer plans are compatible with one another while other combinations do not coordinate, and enrollment into a new plan might terminate or jeopardize eligibility for existing coverage. Further, although there are multiple options for beneficiaries, most individuals are limited in their ability to change plans during the course of the calendar year.

Behind these private plan options, of course, are companies and their contracted agents trying to sell them to Medicare beneficiaries. Some agents and plans are able to exploit the complex choices facing Medicare beneficiaries by steering them towards certain products, regardless of whether it is the best option for an individual. As a result, consumer advocates have found that many people with Medicare have been enrolled in Part D or Medicare Advantage plans they do not understand, did not want, or are inappropriate for their needs. Some have faced greater cost-sharing requirements than their previous coverage, and some have been cut off from doctors who refuse to accept the plan they enrolled in. Some have lost or jeopardized their eligibility for coverage they already had, such as retiree or Medicare supplemental (Medigap) insurance.

PART II

MEDICARE AND MEDICAID FRAUD, WASTE, AND ABUSE

Why GAO did this Study

This report by the Government Accountability Office (GAO) looks at effective implementation of recent laws and agency actions which could help reduce improper payments. This is report GAO-4-409. GAO has designated Medicare and Medicaid as high-risk programs because they are particularly vulnerable to fraud, waste, abuse, and improper payments (payments that should not have been made or were made in an incorrect amount). Medicare is considered high-risk in part because of its complexity and susceptibility to improper payments, and Medicaid because of concerns about the adequacy of its fiscal oversight to prevent inappropriate spending.

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In fiscal year 2015, the Centers for Medicare & Medicaid Services (CMS)- the agency that administers Medicare and Medicaid- estimated that these programs made a total of over \$70 billion in improper payments.

This statement focuses on how implementing prior GAO recommendations and recent laws, as well as other agency actions, could help CMS carry out five key strategies GAO identified in previous reports to help reduce fraud, waste, and abuse and improper payments in Medicare and Medicaid. It is based on 16 GAO products issued from April 2004 through June 2010 using a variety of methodologies, such as analyses of Medicare or Medicaid claims, review of relevant policies and procedures, and interviews with officials. In February 2011, GAO also received updated information from CMS on agency actions.

What the Study Found

The amount of improper payments creates urgency for CMS to effectively implement prior GAO recommendations, provisions in recently enacted laws, and recent guidance related to five key strategies to help reduce fraud, waste, abuse, and improper payments in Medicare and Medicaid.

1. **Strengthening provider enrollment standards and procedures.** Strengthening the standards and procedures for provider enrollment can help reduce the risk of enrolling entities intent on defrauding the program. The Patient Protection and Affordable Care Act as amended (PPACA) strengthens aspects of provider enrollment in Medicare and Medicaid. CMS is implementing these provisions, which include designating providers by levels of risk and providing more stringent review of high-risk providers.
2. **Improving prepayment review of claims.** Prepayment reviews of claims help ensure that Medicare pays correctly the first time. CMS is implementing a PPACA provision requiring states to add automated prepayment controls in their Medicaid programs. In addition, CMS is seeking contractors to apply predictive modeling analysis to claims as a way to develop new prepayment controls to add to Medicare; however, CMS has not implemented certain GAO recommendations related to prepayment review.
3. **Focusing post payment claims review on most vulnerable areas.** Post-payment reviews are critical to identifying payment errors and recouping overpayments. CMS has instituted recovery audit contractor (RAC) programs in Medicare and Medicaid to increase post-payment review. However, CMS contractors generally choose their focus for claims review, and GAO continues to contend that CMS should make it a priority to focus claims administration contractors' post-payment review on the most vulnerable areas.
4. **Improving oversight of contractors.** CMS's oversight of contractors' activities to address fraud, waste, and abuse is critical. CMS has taken action to address GAO recommendations to improve oversight of prescription drug plan sponsors' fraud and abuse programs and to comply with other contractor oversight provisions in PPACA.
5. **Developing a robust process for addressing identified vulnerabilities.** Having mechanisms in place to resolve vulnerabilities that lead to improper payment is critical, but CMS has not developed a robust corrective action process for

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vulnerabilities identified by Medicare RACs, and has not fully implemented GAO recommendations to improve it. Further, CMS's guidance to states on Medicaid RAC programs did not include steps to address vulnerabilities through a corrective action process.

Effective implementation of these recommendations, provisions of law, and guidance will be a key factor in helping to reduce future improper payments.

The purpose of this report is to discuss provisions in recent laws and GAO agency actions that may help reduce fraud, waste, and abuse in the Medicare and Medicaid programs. Fraud, waste, and abuse and improper payments put programs at risk. Fraud represents intentional acts of deception with knowledge that the action or representation could result in an inappropriate gain. Waste includes inaccurate payments for services, such as unintentional duplicate payments. Abuse represents actions inconsistent with acceptable business or medical practices.

An improper payment is any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements. This definition includes any payment to an ineligible recipient, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except where authorized by law), and any payment that does not account for credit for applicable discounts. Pub. L. No. 111-204, § 2(e), 124 Stat. 2224, 2227 (2010) (codified at 31 U.S.C. § 3321 note).

In 1990, GAO began to report on government operations that were identified as “high risk” for serious weaknesses in areas that involve substantial resources and provide critical services to the public. The Secretary of HHS has delegated administration of the Medicare program to the Administrator of CMS. See Appendix I for abbreviations used in this statement.

High-Risk Programs

GAO has designated both Medicare and Medicaid as high-risk programs. Medicare, a federally financed program, was designated as high risk because its complexity and susceptibility to improper payments, added to its size, have made it vulnerable to serious management challenges. The Centers for Medicare & Medicaid Services (CMS)—the agency in the Department of Health and Human Services (HHS) that administers Medicare and oversees Medicaid—has estimated improper payments for Medicare of almost \$48 billion for fiscal year 2010. This estimate does not include improper payments in Part D, the Medicare prescription drug benefit, for which the agency has not yet estimated a total amount. Medicaid, a federal-state program, was designated as high risk in part due to concerns about the adequacy of fiscal oversight, which is necessary to prevent inappropriate spending. Medicaid also has significant improper payments. HHS estimated that the federal share of improper payments in the Medicaid program in fiscal year 2010 was \$22.5 billion. In its *Fiscal Year 2010 Agency Financial Report*, HHS calculated and reported the 3-year (2008, 2009, and 2010) weighted average national payment error rate for Medicaid of 9.4 percent. (See

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Department of Health and Human Services FY 2010 Agency Financial Report
(Washington, D.C.: Nov. 15, 2010).)

Since 2004, GAO has issued 16 products containing strategies it has identified for reducing fraud, waste, abuse, and improper payments in Medicare and Medicaid. This statement updates the previous work in light of certain provisions affecting Medicare and Medicaid in PPACA; the Small Business Jobs Act of 2010; and pertinent agency actions. (Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA), Pub. L. No. 111-152, 124 Stat. 1029, which is referred to collectively as **PPACA**. The program integrity provisions discussed in this statement are generally located in sections 6401 through 6411 and 10603 and 10605 of PPACA as well as section 1304 of HCERA. For previous GAO work, see a list of related products at the end of this statement.

Over the years, the Congress has worked to address fraud, waste, and abuse, and improper payments in the Medicare and Medicaid programs. Beginning in 1997, the Congress provided funds specifically for activities to address fraud, waste, and abuse in federal health care programs. In addition, Congress created the Medicare Integrity Program to conduct activities designed to reduce fraud, waste, abuse, and improper payments in Medicare. The Deficit Reduction Act of 2005 created the Medicaid Integrity Program and included specific appropriations to reduce fraud, waste, and abuse in Medicaid. In 2010, PPACA provided further funding for such efforts and set new requirements specific to Medicare and Medicaid that are designed to address fraud, waste, and abuse. In the same year, the Improper Payments Elimination and Recovery Act of 2010 (IPERA) amended the Improper Payments Information Act of 2002 and established additional government-wide requirements related to accountability, recovery auditing, compliance and noncompliance determinations, and reporting. Implementing guidance has not been issued, and therefore it is too early to assess the implementation of these requirements.

Medicare Parts A and B are known as original Medicare or Medicare FFS. Medicare Part A covers hospital and other inpatient stays. Medicare Part B is optional, and covers hospital outpatient, physician, and other services.

Medicare and Medicaid, reducing improper payments and addressing fraud, waste, and abuse in these programs are continuing challenges for CMS - despite progress made by the agency that GAO has recognized since the programs were first designated as high risk. CMS contractors play an important role in preventing improper payments in Medicare. Within Medicare Parts A and B - also known as Medicare fee-for-service (FFS) - CMS contractors process and pay approximately 4.5 million claims per work day, enroll providers, respond to beneficiary questions, and investigate potential Medicare fraud.

In addition, in Medicare Advantage (Part C) and the Medicare prescription drug benefit (Part D), CMS contracts with private health plans and drug plan sponsors that administer Medicare benefits and in that capacity are responsible for helping to ensure Medicare program integrity. Medicare beneficiaries have the option of obtaining coverage for Part A and B services from private health plans that participate in Medicare

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Advantage - Medicare's managed care program - also known as Part C. All Medicare beneficiaries may purchase coverage for outpatient prescription drugs under Part D.

With more than 50 distinct state-based programs that are partially federally financed, Medicaid creates complex challenges for CMS and states. CMS is responsible for overseeing the program at the federal level, while the states administer their respective programs' operations. Within broad federal requirements, each state operates its Medicaid program in accordance with a state plan. Differences in program design can lead to differences in state programs' vulnerabilities to improper payments and state approaches to protecting the program. States play a critical role in implementing strategies to reduce improper payments and address fraud, waste, and abuse. However, CMS also has a critical role in ensuring that adequate controls are in place and states' actions to help reduce improper payments are effective. Like Medicare, the state Medicaid programs also rely on contractors to help manage payments or services, but they vary in their use of contractors. Today's testimony focuses on how implementing recent laws and prior GAO recommendations, as well as other agency actions, could help CMS carry out five key strategies the GAO identified in previous reports to help reduce fraud, waste, and abuse and improper payments in Medicare and Medicaid. These strategies were identified in the June 2010 testimony as critical to helping prevent fraud, waste, and abuse in Medicare. (See GAO, *Medicare Fraud, Waste, and Abuse: Challenges and Strategies for Preventing Improper Payments*, GAO-10-844T (Washington, D.C.: June 15, 2010)) This statement deals with the challenge of reducing improper payments to providers and plans, but Medicaid has additional areas of concern, such as supplemental payments to providers that can lead to inappropriate federal payments to states. For a discussion of these areas, see GAO, *High Risk Series: An Update*, GAO-11-278 (Washington, D.C.: February 2011).

Past, Present, and Future

This statement discusses past agency actions, actions in progress, and actions that are still needed to implement certain recommendations that the GAO continues to consider important. The five key strategies, and recommendations designed to facilitate them, are taken from the 16 products mentioned above. Twelve of these products, which were issued from April 2004 through June 2010, focused on fraud, waste, abuse, and improper payments in Medicare. Because Medicaid faces a similar challenge to reduce its improper payments, these Medicare strategies can also be helpful when tailored to Medicaid. The other 4 products, which GAO issued since July 2004, focused on reducing fraud, waste, abuse, and improper payments in Medicaid. A list of both sets of products appears at the end of this statement. The products on which this statement is based were developed by using a variety of methodologies, including analyses of Medicare and Medicaid claims, review of relevant policies and procedures, interviews with agency officials and other stakeholders, and site visits. For more detailed information on the methodologies used in the GAO's work, please consult the products listed at the end of this statement.

The GAO also received updated information from CMS in February 2011 on its actions related to the laws, regulations, guidance, and open recommendations that are discussed in this statement. This work was performed in accordance with generally accepted government auditing standards. Those standards require that the GAO plan

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and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for its findings and conclusions based on audit objectives. GAO believes that the evidence obtained provides a reasonable basis for the findings and conclusions based on audit objectives.

Implementation of Prior Recommendations

...and Recent Laws, as Well as Other Agency Actions, Could Help CMS Reduce Medicare and Medicaid Fraud, Waste, and Abuse

The implementation of specific recommendations made in prior GAO reports and provisions in PPACA and the Small Business Jobs Act of 2010, as well as other agency actions, could help in reducing fraud, waste, and abuse in Medicare and Medicaid. In reports issued from 2004 through 2010, GAO has identified five key strategies as important to reducing Medicare and Medicaid fraud, waste, and abuse, and ultimately improper payments:

- strengthening provider enrollment standards and procedures,
- improving prepayment review of claims,
- focusing post-payment claims review on the most vulnerable areas and adding new recovery audit contractors,
- improving oversight of contractors, and
- developing a robust process for addressing identified vulnerabilities.

Vulnerabilities are service-specific errors that result in improper overpayments and underpayments. An example of a vulnerability that leads to improper payments is providers billing for more than one blood transfusion in a hospital outpatient setting for a Medicare beneficiary in a day, which Medicare policy does not allow. PPACA has a number of provisions that could also aid CMS in its efforts to minimize improper payments, and CMS has issued final rules implementing some of these provisions. Furthermore, the Small Business Jobs Act of 2010 and the Presidential Memorandum, "Enhancing Payment Accuracy through a Do Not Pay List," focus on preventing, reducing, and recovering improper payments, which could also help CMS in reducing improper payments in Medicare and Medicaid.

Strengthening Provider Enrollment Procedures

...for Medicare and Medicaid Could Reduce the Risk of Enrolling Providers Intent on Defrauding or Abusing the Program

GAO's work on Medicare indicates that strengthening the standards and procedures for provider enrollment could help reduce the risk of enrolling providers intent on defrauding or abusing the program. Enrolling as a provider in Medicare and Medicaid allows a provider to provide services to beneficiaries and bill for those services. CMS has previously identified two types of providers whose services and items are especially vulnerable to improper payments - home health agencies (HHA) and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). In the 2009 report on HHAs, GAO found problems with the enrollment procedures - for example, CMS's contractors were not requiring HHAs to re-submit enrollment information

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(including information about key officials, operating capital, and practice location) for re-verification every 5 years as required by CMS (See GAO, *Medicare: Improvements Needed to Address Improper Payments in Home Health*, GAO-09-185 (Washington, D.C.: Feb. 27, 2009)). CMS's contractors began to revalidate HHA enrollment during the course of work by GAO on that engagement. In a 2005 report on DMEPOS suppliers, it was found that CMS had not taken sufficient steps to prevent entities intent on defrauding Medicare from enrolling, and GAO reported that more effective screening and stronger enrollment standards were needed to ensure that new suppliers were legitimate businesses (See GAO, *Medicare: More Effective Screening and Stronger Enrollment Standards Needed for Medical Equipment Suppliers*, GAO-05-656 (Washington, D.C.: Sept. 22, 2005)). Partly in response to GAO's recommendation to improve the provider enrollment process, CMS took steps to implement new supplier quality standards as part of an accreditation rule issued in August 2006 and proposed new supplier enrollment standards in January 2008. Suppliers were required to meet these new accreditation standards in 2009; however, the new supplier enrollment standards were not finalized until August 2010. Prior to the implementation of the new supplier enrollment standards, GAO exposed persisting weaknesses when it created two fictitious DMEPOS suppliers, which were subsequently enrolled by CMS's contractor and given permission to begin billing Medicare (See GAO, *Covert Testing Exposes Weaknesses in the Durable Medical Equipment Supplier Screening Process*, GAO-08-955 (Washington, D.C.: July 3, 2008)). As an enrollment requirement, suppliers must, upon request, show that they have contracts for obtaining inventory if the suppliers do not produce their own inventory. Review would have shown that the contracts provided by the fictitious GAO companies had been fabricated.

On February 2, 2011, CMS and the HHS OIG published a final rule to implement these new screening procedures (*Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers*, 76 Fed. Reg. 5862 (Feb. 2, 2011)). The rule is designed to institute a consistent set of enrollment procedures for Medicare and Medicaid, but not to abridge CMS's established screening authority or diminish the screening that providers currently undergo. Therefore, if states have additional Medicaid screening procedures, they will be able to maintain them. In discussing the final rule, CMS noted that Medicare already employs a number of the screening practices described in PPACA to determine if a provider is in compliance with federal and state requirements to enroll or to maintain enrollment in the Medicare program.

Three Levels of Risk

For Medicare, CMS designated three levels of risk—high, moderate, and limited—with different screening procedures for providers at each level. Based in part on GAO's work and that of the HHS OIG and its own experience, CMS designated newly enrolling HHAs and DMEPOS suppliers as high risk and designated other providers at the lower levels. CMS considered issues such as past levels of improper payments and occurrences of fraud among different provider types to determine risk levels. The moderate level comprises re-enrolling HHAs and re-enrolling DMEPOS suppliers; ambulance suppliers; community mental health centers; comprehensive outpatient rehabilitation facilities; hospice organizations; independent diagnostic testing facilities;

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independent clinical laboratories; and physical therapists, including physical therapy groups and portable X-ray suppliers. Other providers, such as physicians and ambulatory surgical centers, are in the limited risk level.

Providers in all risk levels are to be screened to verify that they meet specific requirements established by Medicare. This includes checking providers' licenses, including checks across state lines; and checking certain databases, to verify items such as Social Security numbers, on a pre- and post-enrollment basis to ensure that they continue to meet enrollment criteria. The database checks may include verification of the following: Social Security number; National Provider Identifier; National Practitioner Databank licensure; whether the provider has been excluded from federal health care programs by the OIG; taxpayer identification number; and death of an individual practitioner, owner, authorized official, delegated official, or supervising physician. Moderate- and high-risk providers are also subject to unannounced site visits. All individuals who own a 5 percent or greater interest in high-risk providers are subject to fingerprinting and criminal background checks. In February 2011, CMS told GAO that the agency had requested additional comments on how best to implement the fingerprinting and criminal history record check requirements and might adopt some of the comments in implementing this provision. CMS will not implement fingerprinting and criminal history record checks until after sub-regulatory guidance is published that explains how the agency plans to ensure that privacy rights are respected and that addresses other operational concerns.

CMS's implementation of fingerprinting and criminal history checks would address the 2009 GAO recommendation for CMS to assess the feasibility of verifying the criminal history of all key HHA officials named on the provider enrollment applications.

In its discussion of the February 2, 2011 final rule, CMS indicated that the agency intended to review the criteria for its screening levels on a consistent and ongoing basis and would publish changes if the agency decided to update the assignment of screening levels for Medicare providers. This may become necessary, because fraud is not confined to newly enrolling HHAs and DMEPOS. As more scrutiny is given to these two types of providers, the types of providers that CMS is classifying as moderate risk, such as physical therapy practices, may begin to attract more individuals who are intent on defrauding Medicare or Medicaid. In their 2010 annual report on the Health Care Fraud and Abuse Control Program, DOJ and HHS reported convictions or other legal actions, such as exclusions or civil monetary penalties, against several types of Medicare providers other than DMEPOS suppliers and HHAs, such as medical clinics and physical therapy practices (*The Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2010* (Washington, D.C.: January 2011)).

Adjustment Triggers

CMS has also established triggers for adjustments to an individual provider's risk level. For example, if an individual limited- or moderate-risk provider has been excluded from Medicare by the HHS OIG, that individual provider would move to the high-risk level. For Medicaid, one requirement in CMS's February 2011 rule is that state Medicaid agencies are to establish categorical levels of risk for their providers. For the moderate-

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and high-risk providers, a state Medicaid agency must conduct site visits, and for high-risk providers, it must conduct fingerprinting and criminal background checks.

In addition to enhancing screening procedures, PPACA includes two provisions that strengthen other aspects of provider enrollment for Medicare and Medicaid. CMS implemented these provisions in its February 2011 final rule. First, PPACA allows CMS to declare a moratorium on enrollment of new Medicare and Medicaid providers when the agency determines such a moratorium to be necessary to prevent or combat fraud, waste, and abuse. State Medicaid agencies may also authorize such a moratorium. Second, PPACA also requires state Medicaid programs to terminate providers that have been terminated from Medicare or other state Medicaid programs.

PPACA also imposes new requirements on Medicare and Medicaid providers, including a requirement for establishing compliance programs that adhere to standards established by the Secretary in consultation with the OIG.³²³²In general, a compliance program is the internal set of policies, processes, and procedures that a provider organization implements to help it act ethically and lawfully. In this context, compliance plans help provider organizations prevent and detect violations of Medicare laws and regulations. CMS sought public comment on establishing such compliance programs in a proposed rule on September 23, 2010 (*Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers*. 75 Fed. Reg. 58204 (Sept. 23, 2010)).

The agency indicated in explaining its February 2011 final rule that it intended to conduct further rulemaking on compliance program requirements and would advance specific proposals in the future. In addition, PPACA imposes specific requirements for providers to disclose any current or previous affiliation with a provider that has uncollected debt; has been or is subject to a payment suspension under a federal health care program; has been excluded from participation under Medicare, Medicaid, or CHIP or has had its billing privileges denied or revoked. The law allows CMS to deny enrollment to any such provider whose previous affiliations pose an undue risk. In February 2011, CMS stated that it was drafting a proposed rule to implement this authority. Further, providers that order home services must have a face-to-face encounter with the beneficiary before the services can be ordered. CMS issued a final rule regarding this requirement in November 2010 (*Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices*. 75 Fed. Reg. 70,372 (Nov. 17, 2010)). Finally, providers that order DMEPOS or home health services for beneficiaries will have to be enrolled in Medicare or Medicaid and maintain documentation on the services or items ordered, and the claims for these services and items must contain their National Provider Identifier number.

Legitimacy of Providers

Before PPACA, CMS had taken other steps over the past 3 years regarding the legitimacy of providers, and PPACA has provisions that are consistent with some of these steps. First, the agency implemented a statutory requirement for DMEPOS suppliers to post a surety bond to help Medicare recoup erroneous payments that result from fraudulent or abusive billing practices (Social Security Act §1834(a)(16)(B)). As of

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October 2009, DMEPOS suppliers were required to obtain and submit a surety bond in the amount of at least \$50,000. A DMEPOS surety bond is a bond issued by an entity guaranteeing that a DMEPOS supplier will fulfill its obligation to Medicare. If the obligation is not met, Medicare will recover its losses via the surety bond (Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 74 Fed. Reg. 166 (Jan. 2, 2009)).

PPACA extended CMS's authority to impose surety bonds consistent with billing volume to all Medicare providers. Before PPACA, the Social Security Act also required CMS to impose surety bonds on HHAs and permitted the imposition of surety bonds on certain other Medicare providers. PPACA requires any surety bond imposed to be commensurate with the provider's billing volume. CMS officials stated that the agency is drafting a rule to implement this authority, in which the agency will propose imposing surety bonds on additional providers.

Second, as directed by law, CMS required that all DMEPOS suppliers be accredited by a CMS-approved accrediting organization to ensure that they meet minimum standards. In June 2010, CMS said that approximately 9,000 DMEPOS suppliers were dis-enrolled as result of these surety bond and accreditation requirements. Third, CMS began to implement a Medicare competitive bidding program for durable medical equipment and supplies with prices that took effect in January 2011 from the first round of bidding. This program could also help reduce fraud, waste, and abuse because it requires CMS to select DMEPOS suppliers based in part on new scrutiny of their financial documents and other application materials, among other things. The program took effect initially in nine metropolitan areas. PPACA built upon some of these efforts. It required CMS to speed up implementation of the competitive bidding program, expanding the number of areas to be included in the second round of bidding from 70 to 91 by the end of 2011.

Improving Prepayment Review

...of Claims Could Prevent Improper Payments from Being Made

GAO's work on Medicare has shown that prepayment reviews of claims are essential to help ensure that Medicare pays correctly the first time. Conducting these reviews is challenging due to the volume of claims. Overall, less than 1 percent of Medicare's claims are subject to a medical record review by trained contractor personnel.

Therefore, having robust automated payment controls - called edits - in place that can deny inappropriate claims or flag them for further review is critical. However, GAO has found weaknesses in these prepayment controls. For example, in 2007, it was found that contractors responsible for reviewing DMEPOS claims did not have automated prepayment controls in place to identify questionable claims, such as those associated with atypically rapid increases in billing or for items unlikely to be prescribed in the normal course of medical care (See GAO, *Medicare: Improvements Needed to Address Improper Payments for Medical Equipment and Suppliers*, GAO-07-59 (Washington, D.C.: Jan. 31, 2007)).

Lack of such prepayment controls has resulted in losses to Medicare. For example, GAO found that from the first quarter of 2003 through the first quarter of 2005, due to an absence of such prepayment controls, 225 suppliers increased their billing to Medicare both by at least 500,000 and by at least 50 percent from at least one 3-month period to

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the next. In November 2004, the U.S. government won a default civil judgment against 16 of these suppliers for filing false claims against Medicare for services not rendered - after they were paid almost \$40 million from January 2003 through September 2004.

As a result, GAO recommended in 2007 that CMS require its contractors to develop thresholds for unexplained increases in billing and use them to develop automated prepayment controls. Although CMS has not implemented that recommendation specifically, it has added edits to flag claims for services unlikely to be provided in the normal course of medical care. Additional prepayment controls, such as those based on thresholds for unexplained increases in billing, could further enhance CMS's ability to identify improper claims before they are paid.

PPACA requires state Medicaid agencies to add some specific prepayment edits. Beginning with claims submitted on October 1, 2010, PPACA requires states to incorporate into their Medicaid Management Information System compatible National Correct Coding Initiative (NCCI) methodologies in order to promote correct coding and to control improper coding leading to inappropriate payment. NCCI, a CMS program that consists of coding policies and edits, was initiated for Medicare in 1996 to help ensure correct payment for Medicare Part B for physician, laboratory, and radiology services claims. Under NCCI, CMS's contractors screen Medicare Part B claims with automated prepayment edits designed to detect anomalies that indicate a claim has incorrect information.

These methodologies are in use in the Medicare program for edits related to certain practitioner services, ambulatory surgical center services, outpatient hospital services, and supplier claims for durable medical equipment. For example, NCCI edits can detect claims with duplicate services delivered to the same beneficiary on the same date of service, such as more than one excision of a gallbladder for the same beneficiary. CMS provided guidance on how to implement this requirement through a state Medicaid directors' letter issued on September 1, 2010.

Claims Review

The Small Business Jobs Act of 2010 also has a provision regarding claims review to prevent improper payments. It requires CMS to use predictive modeling and other analytic techniques - known as predictive analytic technologies - both to identify and to prevent improper payments under the Medicare FFS program. The law requires these predictive analytic technologies to be integrated into the Medicare FFS claims flow and prevent the payment of claims identified as potentially fraudulent, wasteful, or abusive until the claims can be verified as valid.

The law requires these predictive analytic technologies to be used to analyze and identify Medicare provider networks, billing patterns, and beneficiary utilization patterns and detect those that represent a high risk of fraudulent activity. Through such analysis, unusual or suspicious patterns or abnormalities could be identified that could be used to prioritize additional review of suspicious transactions before payment is made. CMS published a solicitation in December 2010 for these technologies and a case management system to track findings. The law requires that the solicitation require contractors that are selected to begin using these technologies on July 1, 2011, in the

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10 states identified by CMS as having the highest risk of waste, fraud, or abuse in Medicare FFS payments. After the initial year, based on the results of the predictive analytic technologies, their use will be expanded to other states. Based on the results after year 3, the technologies are to be expanded to Medicaid. In September 2010, CMS indicated that it was conducting pilots to test the ability of the technologies to identify potential fraud in paid claims. Agency officials made known that the experience from the pilot projects helped them develop the solicitation. CMS reported that it planned to incorporate the technologies for prepayment review after testing them through post-payment review to ensure that the new technologies work as intended and do not disrupt claims from legitimate providers or diminish access to care for legitimate beneficiaries.

In addition, a June 2010 Presidential Memorandum directed agencies to check certain databases—known as the “Do Not Pay List”—before making payments, to ensure that payments did not go to individuals who were dead or excluded from receiving federal payments or to entities that had been excluded from receiving federal payments. CMS officials stated that, in response to the Presidential Memorandum, the agency reviewed the databases that it and its Medicare contractors were using to determine payment eligibility for providers and took action to ensure that the agency’s method of ensuring payment eligibility was consistent with the intent of the “Do Not Pay List”. Specifically, CMS told GAO that it is currently reviewing the following databases: (1) the Social Security Administration’s (SSA) Death Master File, (2) HHS OIG’s Exclusions Database, (3) the Federal Payment Levy Program (FPLP), (4) the Treasury Offset Program, and (5) General Services Administration’s Excluded Parties List System (EPLS)

Provider Enrollment System

CMS reported that it uses information from these databases to update its provider enrollment system. Specifically, provider enrollment information is checked monthly against the Medicare Exclusion Database, which contains information from the HHS OIG’s Exclusions Database, the GSA’s EPLS, and the SSA’s Death Master File to update providers’ enrollment status. Agency officials said that CMS’s contractors integrate updated provider enrollment information into CMS’s payment system. Specifically, changes in CMS’s provider enrollment system are downloaded nightly to the CMS contractors that pay claims. These contractors include Medicare Administrative Contractors (MAC) and any fiscal intermediaries or carriers still administering claims. These MACs, carriers, and fiscal intermediaries are responsible for ensuring that they only pay claims to eligible providers.

Claims are then run through prepayment edits to check that providers are active and eligible for payment. With regard to Medicaid, CMS officials said that the state programs use some of these data sets, such as SSA’s Death Master File, but that the states’ abilities to complete checks consistent with the Presidential Memorandum would depend on whether they could obtain access to other databases, such as the FPLP, which has information on federal tax debt. The CMS officials added that they have encouraged states to review the databases available to them prior to making payments.

Focusing Post-payment Claims Review

...on the Most Vulnerable Areas and Adding New Recovery Audit Contractors Could Increase Identification of Improper Payments

GAO has found that post-payment reviews are critical to identifying payment errors to recoup overpayments in Medicare and that there are steps that could strengthen post-payment review. These steps involve focusing post-payment claims review on the most vulnerable areas and increasing the amount of post-payment review by using recovery audit contractors (RAC) for the Medicare and Medicaid programs. CMS's claims administration contractors conduct limited post-payment reviews; therefore, it is important that they target their post-payment review resources on providers with a demonstrated high risk of improper payments. GAO reported in 2009 that two contractors paying home health services claims conducted post-payment reviews on fewer than 700 of the 8.7 million claims they paid in fiscal year 2007 (See GAO-09-185).

For example, in 2009 GAO recommended that post-payment reviews be conducted on claims submitted by HHAs with high rates of improper billing identified through prepayment review (See GAO-09-185). To date, CMS has not implemented this recommendation; however, in February 2011 CMS stated that its contractors are developing medical review strategies that may include post-payment reviews on HHAs. The GAO continues to believe that focusing post-payment claims review on the most vulnerable areas should be a priority. Cross-checking claims for home health services with the physicians who prescribed them can be a further safeguard against fraud, waste, and abuse, but, as reported in 2009, this is not routinely done (See GAO-09-185).

For example, a physician must certify that a beneficiary needs home health services before services can be provided, but CMS does not routinely provide physicians with information that would enable a physician to determine whether an HHA was billing for services that the physician had not authorized or services that the physician would not consider necessary for the beneficiary's care. GAO recommended that CMS require that physicians receive a statement of services beneficiaries received based on the physicians' certification, but to date, the agency has not taken action. Taking such action also could be beneficial for other services and items susceptible to fraud and abuse that are not billed directly by physicians, such as DMEPOS. In February 2011, CMS indicated that it did not plan to implement this recommendation because agency officials thought that it would involve extensive resources to do so.

Post Payment Review

Prior to PPACA, CMS had efforts focusing on post-payment review of claims, especially its new national RAC program, which began in March 2009, after completion of a 3-year demonstration program in 2008. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 directed CMS to conduct a project to demonstrate how effective the use of RACs would be in identifying underpayments and overpayments, and in recouping overpayments in Medicare (Pub. L. No. 108-173, § 306, 117 Stat. 2066, 2256. Subsequently, in December 2006 the Tax Relief and Health Care Act of 2006 required CMS to implement a national RAC program by January 1, 2010. Pub. L. No. 109-342, div. B, title III, § 302, 120 Stat. 2924, 2991 (codified at 42 U.S.C. § 1395ddd(h))).

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The national program is designed to help the agency supplement the post-payment reviews conducted by contractors other than RACs. The RACs review Part A and B claims after payment, but because RACs are paid a contingent fee based on the dollar value of the improper payments identified, they have focused on claims from inpatient hospital stays, which are generally more costly services. GAO pointed out to CMS in previous work that other contractors' post-payment review activities could be more valuable if CMS directed these contractors to focus on items and services where RACs are not expected to focus their reviews, and where improper payments are known to be high, such as home health services claims (See GAO, *Medicare Fraud, Waste and Abuse: Challenges and Strategies for Preventing Improper Payments*, GAO-10-844T (Washington, D.C.: June 15, 2010)).

PPACA expands Medicare's RAC program to Parts C and D. CMS published a request for comments on the development of Parts C and D RACs in December 2010. CMS awarded a Part D RAC task order for a 1-year base period that began January 2011 and 4 option years.

PPACA also requires state Medicaid programs to establish contracts, consistent with state law and similar to the contracts established for the Medicare RAC program, with one or more RACs. These state RACs are to identify underpayments and identify and recoup overpayments made for services provided by state Medicaid programs. In November 2010, CMS issued a proposed rule and guidance to states on establishing a Medicaid Recovery Audit Contractor program. CMS's proposed rule covered issues such as contingency fees and establishing a process for provider appeals of RAC determinations. States can ask CMS for an exception to the Medicaid RAC requirements. CMS officials told GAO that as of February 2011, 55 state Medicaid agencies have submitted their plans for addressing the Medicaid RAC PPACA provision, and 14 states have asked for exceptions in part or in whole. CMS plans to make public its decisions on any exceptions granted.

Improving Oversight of Contractors

...Could Help Ensure That Safeguard Activities Are Conducted

Overseeing the activities of contractors that provide services to Medicare beneficiaries is critical to addressing fraud, waste, and abuse and preventing improper payments. Over the years, areas have been found where CMS's oversight had been insufficient to ensure that required program control activities were conducted and working well. For example, all Part D drug plan sponsors are required to have programs to detect, correct, and prevent fraud, waste, and abuse—also referred to as fraud and abuse programs. CMS is responsible for ensuring that sponsors are in compliance with this requirement; however, in 2008 GAO found that CMS's oversight of these programs had been limited (GAO, *Medicare Part D: Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited*, GAO-08-760 (Washington, D.C.: July 21, 2008)).

Timely Audits

GAO recommended that CMS conduct timely audits of sponsors' fraud and abuse programs. CMS agreed with this recommendation, and in March 2010 it was reported that CMS had completed desk audits of selected sponsors' programs and was beginning to implement an expanded oversight strategy, including on-site audits to assess the effectiveness of these programs more thoroughly (See *Medicare Part D: CMS Oversight of Part D Sponsors' Fraud and Abuse Programs Has Been Limited, but CMS Plans Oversight Expansion*. GAO-10-481T (Washington, D.C.: March 3, 2010)). A desk audit includes reviews of requested documents only, in contrast to site visits, which include other tasks, such as interviews with sponsor officials.

In November 2010, CMS officials reported that the agency had conducted on-site audits of 33 of the 290 sponsors in 2010, which covered 62 percent of the enrolled beneficiaries in 2010. As a result of the on-site audits, CMS had taken formal enforcement actions against several sponsors. In addition, CMS published a final rule in April 2010 to increase its oversight efforts and ensure that sponsors have effective programs in place (*Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 75 Fed. Reg. 19,678 (Apr. 15, 2010)).

PPACA included new requirements for CMS to evaluate contractors receiving Medicare Integrity Program and Medicaid Integrity Program funding every 3 years. In addition, PPACA requires these contractors to provide performance statistics to HHS and OIG upon request. These statistics may include the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment of such activities. In February 2011, CMS officials stated that they are taking action to implement these requirements for Medicare and Medicaid. For Medicare, CMS reported that it is currently tracking performance statistics and is adding to and refining these statistics. CMS is also currently developing the specific performance statistics for its Part D integrity contractors and expects to finalize these statistics this year. For Medicaid, CMS also reported that it is requiring states to track performance statistics and anticipates finalizing the specific performance statistics to be tracked by March 2011.

Developing a Robust Process

...for Addressing Identified Vulnerabilities Could Help Reduce Improper Payments
Having mechanisms in place to resolve vulnerabilities that lead to improper payment is critical to effective program management, but work has shown that CMS has not developed a robust process to specifically address identified vulnerabilities that lead to improper payments in Medicare. GAO has reported that an agency should have policies and procedures to ensure that (1) the findings of all audits and reviews are promptly evaluated, (2) decisions are made about the appropriate response to these findings, and (3) actions are taken to correct or resolve the issues promptly.

Internal Control

These are all aspects of internal control, which is the component of an organization's management that provides reasonable assurance that the organization achieves effective and efficient operations, reliable financial reporting, and compliance with

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applicable laws and regulations. Internal control standards provide a framework for identifying and addressing major performance challenges and areas at greatest risk for mismanagement. (GAO, *Internal Control Standards: Internal Control Management and Evaluation Tool* GAO-01-1008G (Washington, D.C.: August 2001).

GAO has also stressed the importance of holding individuals accountable for achieving agency objectives. As reported in March 2010, CMS did not establish an adequate process during its recovery audit contracting demonstration or in planning for the national program to ensure prompt resolution of identified improper payment vulnerabilities in Medicare. *Medicare Recovery Audit Contracting: Weaknesses Remain in Addressing Vulnerabilities to Improper Payments, Although Improvements Made to Contractor Oversight*, GAO-10-143 (Washington, D.C.: March 31, 2010).

During the demonstration, CMS did not assign responsibility to agency officials or contractors for taking corrective action. According to CMS officials, the agency took corrective action only for vulnerabilities with national implications, and let the contractors that processed and paid claims decide whether to take action for vulnerabilities that might occur only in certain geographic areas. Additionally, during the demonstration CMS did not specify in a plan what type of corrective action was required or establish a time frame for corrective action. The documented lack of assigned responsibilities impeded CMS's efforts to promptly resolve the vulnerabilities identified during the demonstration.

For the national Medicare RAC program, although CMS established a corrective action team to compile, review, and categorize identified vulnerabilities and discuss corrective action recommendations, the corrective action process is still incomplete. CMS appointed the Director of the Office of Financial Management to be responsible for the day-to-day operations of the program, and the CMS Administrator to be responsible for vulnerabilities that span agency components. However, the corrective action process still does not include any steps to either assess the effectiveness of the corrective actions taken or adjust them as necessary based on the results of the assessments. Further, the agency has not developed time frames for implementing corrective actions.

Corrective Action Process

Because of these weaknesses, GAO recommended that CMS develop and implement a corrective action process that includes policies and procedures to ensure that the agency promptly (1) evaluates findings of RAC audits, (2) decides on the appropriate response and a time frame for taking action based on established criteria, and (3) acts to correct the vulnerabilities identified.

CMS concurred with this recommendation. Agency officials said they intended to review vulnerabilities on a case-by-case basis and were considering assigning them to risk categories to help prioritize their actions. Implementation of this recommendation is a work in process, CMS reported that the agency is working to address the vulnerabilities identified during the demonstration program. Specific to corrective actions, CMS told GAO that it now requires its contractors to consider and evaluate vulnerabilities identified by various entities, including the RACs.

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For the Medicaid RAC program, CMS's proposed rule for state Medicaid programs does not include any steps to collect information on vulnerabilities to improper payment and develop a corrective action process to address them. Lessons learned from the Medicare RAC program indicate that collecting information on vulnerabilities and having an adequate corrective action process are important to address vulnerabilities. In turn, this suggests that having Medicaid RACs report to state Medicaid agencies and CMS on the vulnerabilities they identify and having a corrective action process to address those vulnerabilities would be important to reduce Medicaid improper payments. State Medicaid agencies are required to have a corrective action process as part of their activities to reduce their Medicaid error rates. Information from the Medicaid RAC program could be incorporated into these processes. Although its guidance was silent on this issue, in February 2011, CMS said that state Medicaid programs will be responsible for addressing RAC-identified vulnerabilities and that it will monitor and assist states in implementing corrective actions.

Concluding Observations

The amount of improper payments in the Medicare and Medicaid programs creates urgency for CMS to act decisively to reduce them. Identifying the nature, extent, and underlying causes of improper payments is an essential prerequisite to reducing them, as is implementing prior GAO recommendations to develop an adequate corrective action process to address vulnerabilities. CMS could also take other actions to help better address the issue of fraud, waste, abuse, and improper payments in the Medicare and Medicaid programs. For Medicare, these include (1) developing thresholds for unexplained increases in billing and using them to develop automated prepayment controls, (2) conducting post-payment reviews on claims submitted by HHAs with high rates of improper billing identified through prepayment review, (3) cross-checking claims for home health services with the physicians who prescribed them, and (4) focusing claims administration contractors' post-payment reviews on items and services where RACs are not expected to focus their reviews, and where improper payments are known to be high. For Medicaid, other actions include ensuring that states develop adequate corrective action processes to address vulnerabilities to improper Medicaid payments to providers and issuing guidance to states to better prevent payment of improper claims for controlled substances.

As it implements PPACA provisions concerning Medicare and Medicaid, CMS has an opportunity to address fraud, waste, abuse, and improper payments in the two programs. CMS has made progress in rulemaking and issuing guidance to implement this law, the Small Business Jobs Act, and the "Do Not Pay List" memorandum. CMS's implementation efforts are in process, so it is too early to gauge their effects. As these requirements become part of Medicare and Medicaid operations, additional evaluation and oversight will help determine whether they are implemented as intended and have the desired effect on better ensuring proper payment. As the implementation process proceeds, GAO continues to monitor these issues. Notably, it is beginning new work to assess CMS's efforts to strengthen the standards and procedures for Medicare provider enrollment to reduce the risk of enrolling providers that are intent on defrauding or abusing the program. GAO also plan to examine the effectiveness of different types of prepayment edits in Medicare and of CMS's oversight of its contractors in implementing those edits to help ensure that Medicare pays claims correctly the first time. The level of

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importance placed on effectively implementing GAO recommendations and the requirements established by recent laws and guidance will be a key factor in reducing improper payments in the Medicare and Medicaid programs and ensuring that federal funds are used efficiently and for their intended purposes.

PART III

Centers for Medicare and Medicaid Services

Prescription Drug Benefit Manual

Part D program to Control Fraud, Waste and Abuse

This section is a review of the CMS program to control fraud, waste and abuse. This chapter provides both interpretative rules and guidelines for Part D plan sponsors on how to implement the regulatory requirements under 42 C.F.R. §423.504(b)(4)(vi)(H) to have in place a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste, and abuse as an element of their compliance plan. While CMS regulations require Sponsors to implement a comprehensive fraud and abuse program, the adoption of the methods suggested within this chapter on how to implement a comprehensive fraud and abuse program are left to the discretion of each Sponsor. Additionally, this chapter outlines CMS' guidelines for operational issues such as handling complaints and coordinating with CMS and law enforcement.

Prescription Drug Benefit Manual

Part D Program to Control Fraud, Waste and Abuse

This chapter provides both interpretive rules and guidelines Part D plan sponsors (hereinafter "Sponsors") on how to implement the regulatory requirements under 42 C.F.R. § 423.504(b)(4)(vi)(H) to have in place a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse as an element of their compliance plan. While CMS regulations require Sponsors to implement a comprehensive fraud and abuse program, the adoption of the methods suggested within this chapter on how to implement a comprehensive fraud and abuse program are left to the discretion of each Sponsor.

Additional information related to Part D Program Integrity and fraud, waste and abuse may be found at <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/>.

Please note that this manual chapter does not address or provide guidance for Medicare Advantage (MA) issues that do not relate to the Medicare Part D prescription drug benefit. MA organizations should consult the Medicare Managed Care Manual for issues related to the Part C benefit.

Definition of Terms Used in this Chapter

For the illustrative purposes of this manual only, the following terms are generally defined as follows. For the legally operative definitions of some of these terms, please see applicable statutes, regulations, and published HHS-OIG Compliance Guidance, if any. Unless otherwise stated in this Chapter, the following definitions apply:

Act: The Social Security Act and titles referred to as titles of any other Act.

Administrator: The Administrator of the Centers for Medicare & Medicaid Services.

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Appeal: A process whereby a person with Medicare (or such person's representative) exercises the right to request a review of a contractor claim determination to deny Medicare coverage or payment for a service in full or in part.

Audit: An audit refers to a formal review of compliance with a particular set of internal (e.g., policies and procedures) or external (e.g., laws and regulations) standards used as base measures.

Brand Name Drug: A drug for which an application is approved under Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(c)), including an application referred to in Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). (See 42 C.F.R. § 423.4).

Centers for Medicare and Medicaid Services (CMS): CMS means the Centers for Medicare and Medicaid Services, an Agency within the Department of Health and Human Services.

Contractor: Any person or entity that directly contracts with CMS to provide items or services or perform tasks related to the Medicare Program. Contractor includes all PDPs, MA-PDs, Fallbacks, Cost Plans, MEDICs, Program Safeguard Contractors (PSCs), Durable Medical Equipment Regional Carriers (DMERCs), fiscal intermediaries, carriers, Medicare Administrative Contractors (MACs) and Regional Home Health Intermediaries (RHHIs).

Cost Plan: A drug benefit plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act. (See 42 C.F.R. § 417.1, § 423.4).

Data Analysis: Data analysis is a tool for identifying potential payment errors and trends in utilization, referral patterns, formulary changes, and other indicators of potential fraud, waste or abuse, as well as in investigating cases of potential fraud, waste or abuse once identified. Data analysis compares claim information and other related data (e.g., the provider registry) to identify potential errors and /or potential fraud by claim / prescription drug event characteristics (e.g., drugs provided, diagnoses, providers, or beneficiaries) individually or in the aggregate. Data analysis is an integrated, on-going component of fraud detection and prevention activity.

The Department (DHHS): DHHS means the Department of Health and Human Services.

Department of Justice (DOJ): DOJ means the Department of Justice.

Edit: Logic within the Sponsor claims processing system that selects certain claims, evaluates or compares information on the selected claims or other accessible source, and depending on the evaluation, takes action on the claims, such as pay in full, pay in part, or suspend for manual review.

E-Prescribing: The transmission in electronic form of a prescription(s), information on a beneficiary's eligibility for drug benefits, medication history, and related health information between prescriber, dispenser, PBM, health plan, or other related entity either directly or through an e-prescribing network.

Employer Plans: PDP or MA-PD plans, sponsored by employers/unions, which have contracted directly with CMS to become prescription drug plans or Medicare Advantage plans for their own members, pursuant to a CMS waiver. Also includes plans being offered and sold to employer/union groups by PDPs, MA Organizations, and Cost Plan Sponsors, pursuant to CMS waivers.

Fallback Prescription Drug Plan (Fallback, Fallback Plan): A prescription drug plan offered by a fallback entity, as governed by 42 C.F.R. § 423.851-875, that:

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- Offers only defined standard or actuarially equivalent standard prescription drug coverage as defined in 42 C.F.R. § 423.100;
- Provides access to negotiated prices, including discounts from manufacturers; and
- Meets all other requirements established for prescription drug plans, except as otherwise specified by CMS in regulation or in separate guidance.

Federal Bureau of Investigation (FBI): FBI means the Federal Bureau of Investigation.

Formulary: The entire list of Part D drugs covered by a Part D plan.

Low Income Subsidy: A program to provide low-income Medicare beneficiaries with extra assistance with premium and cost sharing under Part D. Low-income subsidy applicants who are not deemed eligible for the subsidy will have to meet an income and asset test, and eligibility will be determined by either the State Medicaid Agency or the Social Security Administration. Beneficiaries may fall into two groups: those who qualify for full subsidy with no coverage gap and nominal cost sharing, and those beneficiaries who qualify for other low-income benefits with reduced deductibles and coinsurance and sliding scale premium subsidies (note these individuals have incomes/assets valued higher than those receiving the full subsidy). (See 42 C.F.R. § 423 Subpart P).

Medicare Advantage (MA): A public or private entity organized and licensed by a state as a risk-bearing entity (with the exception of provider sponsored organization receiving waivers) that is certified by CMS as meeting the Medicare Advantage contract requirements. (See 42 C.F.R. § 422.2).

Medicare Advantage Prescription Drug Plan (MA-PD): An MA plan that provides qualified prescription drug coverage. (See 42 C.F.R. § 423.4).

Medicare Drug Integrity Contractor (MEDIC): An organization that the CMS has contracted with to perform specific program integrity functions for Part D under the Medicare Integrity Program. The MEDIC is CMS' designee to manage CMS' audit, oversight, and anti-fraud and abuse efforts in the Part D benefit.

Medicaid: Medical assistance provided under a state plan approved under Title XIX of the Act.

Medical Review: Involves a thorough assessment of the medical record documentation associated with a specific claim. Medical review can be conducted on a pre- or post payment basis. A pre-payment review may be used as part of the pre-authorization process for specific drugs. Post payment medical review, when used for medical necessity probe reviews, provides valuable information into the prescribing practices of providers and may identify overpayments.

Medicare: The health insurance program for the aged and disabled under Title XVIII of the Act.

Monitoring Activities: Reviews that are repeated regularly during the normal course of operations. Monitoring activities may occur to ensure corrective actions are undertaken or when no specific problems have been identified to confirm ongoing compliance.

Office of the Inspector General (OIG): OIG means the Office of the Inspector General for the Department of Health and Human Services.

Part D Eligible Individual: An individual who is entitled to Medicare benefits under Part A or enrolled in Part B and lives in the Part D plan's service area pursuant to 42 C.F.R. § 423.30(a). (See 42 C.F.R. § 423.4).

Part D Plan: A prescription drug plan (PDP), an MA-PD plan, or a PACE plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. This includes employer- and union-sponsored plans. (See 42 C.F.R. § 423.4).

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Part D Plan Sponsor: Refers to a PDP Sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage. This includes employer- and union-sponsored plans. (See 42 C.F.R. § 423.4).

Pharmacy Benefit Manager (PBM): An entity that provides pharmacy benefit management services, including contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; performing drug utilization review; and operating disease management programs. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies.

Pharmacy & Therapeutics (P&T) Committee: A committee, the majority of whose members shall consist of individuals who are practicing physicians or practicing pharmacists (or both), that is charged with developing and reviewing a formulary. Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom is independent and free of conflict with respect to the Sponsor and at least one practicing physician and at least one practicing pharmacist who have expertise in the care of elderly or disabled persons. (See 42 C.F.R. § 423.120(b)(1)).

Program of All-Inclusive Care for the Elderly (PACE): A capitated benefit authorized by the Balanced Budget Act of 1997 (BBA) that features a comprehensive medical and social service delivery system and integrated Medicare and Medicaid financing.

Prescription Drug Plan (PDP): Prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 C.F.R. § 423.272 to offer qualified prescription drug coverage. (See 42 C.F.R. § 423.4).

Provider: Any Medicare provider or supplier (for example, hospital, skilled nursing facility, home health agency, outpatient physical therapy, comprehensive outpatient rehabilitation facility, renal dialysis facility, hospice, physician, non-physician practitioner, laboratory, supplier, pharmacy, pharmacist). (See www.cms.hhs.gov/apps/glossary/default.asp.) The term provider is generally used in this Chapter to refer only to individuals or organizations that prescribe or supply prescription drugs that are reimbursable under Part D. If references apply to specific types of providers only (e.g. pharmacists), the specific provider type will be identified.

Recoupment: The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Reinsurance: The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross prescription drug costs incurred in the coverage year after the individual has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold specified in 42 C.F.R. § 423.104(d)(5)(iii). (See 42 C.F.R. § 423.329(c)).

Risk Corridors: Specified risk percentages above and below the target amount. For each year, CMS establishes a risk corridor for each Part D plan. Risk corridors will serve to decrease the exposure of plans where allowed costs exceed plan payments for the basic Part D benefit. (See 42 C.F.R. § 423.336(a)(2)).

Symmetrical risk corridors means that the same size corridors exist below the target amount as above it. The actual upper or lower limits of each corridor equal the target

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amount plus or minus the product of the risk percentage times the target amount. Plans would always be at full financial risk for all spending on supplemental drug coverage.

State Pharmaceutical Assistance Program (SPAP): A State program that provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals. (See Section 1860-D23 of the Act; 42 C.F.R. § 423.464(e)).

Secretary: The Secretary of the Department of Health and Human Services.

Service Area: For a prescription drug plan an area established in 42 C.F.R. § 423.112(a) within which access standards under § 423.120(a) are met. For an MA-PD plan, an area that meets the definition of MA service area as described in § 422.2, and within which access standards under § 423.120(a) are met. For a fallback prescription drug plan, the service area described in § 423.859(b). Service area does not include facilities in which individuals are incarcerated. (See 42 C.F.R. § 423.4).

TrOOP (True Out of Pocket Costs): The amount a beneficiary must spend on Part D covered drugs to reach catastrophic coverage. It is based on the standard benefit design \$250 deductible + \$500 beneficiary coinsurance during initial coverage + \$2850 coverage gap = \$3600 (these numbers are for 2006 and will increase by law in subsequent years). Payments counting toward TrOOP include payments by beneficiary, family member or friend, SPAP, a charity, or a personal health savings vehicle (flexible spending account, health savings account, medical savings account). Payments that do NOT count toward TrOOP include Part D premiums and coverage by other insurances, group health plans, government programs (non-SPAP), workers' compensation, Part D plans' supplemental or enhanced benefits, or other third parties.

20 - Overview of Fraud, Waste and Abuse

All Sponsors are required to have a comprehensive plan to detect, correct and prevent fraud, waste and abuse (42 C.F.R. § 423.504(b)(4)(vi)(H)). This requirement is listed as one of the compliance plan elements in the *Medicare Prescription Drug Benefit* regulations published on January 28, 2005 (70 Fed. Reg. 4194 (2005)). The regulations list the core elements of a compliance plan, including the requirement to have in place a comprehensive fraud, waste and abuse program (42 C.F.R. § 423.504(b)(4)(vi)). The specific requirements of the compliance program for the Part D benefit include:

1. Written Policies and Procedures and Standards of Conduct
2. Compliance Officer and Compliance Committee
3. Training and Education
4. Effective Lines of Communication
5. Enforcement of Standards through well publicized disciplinary guidelines
6. Monitoring and Auditing
7. Corrective Action Procedures
8. Comprehensive Fraud and Abuse Plans - Procedures to voluntarily self-report potential fraud or misconduct

The purpose of this chapter is to assist Sponsors in implementing a comprehensive program to prevent and detect fraud, waste and abuse in the prescription drug program pursuant to both statutory and regulatory authorities (42 U.S.C. § 1395w-104; 42 C.F.R. § 423.505(b)(4)(vi)(H)). Specifically, this chapter provides recommendations for Sponsors to implement a program to control fraud, waste and abuse as part of an effective Part D compliance program. Additionally, this chapter outlines CMS' guidelines

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for operational issues such as handling complaints, and coordinating with CMS and law enforcement. While CMS regulations require Sponsors to implement a comprehensive fraud and abuse plan, the adoption of the approaches suggested within this chapter on how to implement a comprehensive fraud and abuse plan is left to the discretion of each Sponsor based on the size, scope and resources of its organization.

It is worth noting that for many Sponsors, traditional fraud, waste and abuse programs have been aimed at the conduct of third parties submitting claims to the Sponsor and are often implemented by Special Investigation Units (SIUs), whereas their compliance programs typically encompass the organization's efforts to monitor itself and its subcontractors with respect to contract regulations and compliance with applicable laws and regulations. However, CMS does not interpret the requirement to have in place a program to control fraud, waste and abuse to be limited to the conduct of third parties submitting claims to the Sponsor (42 U.S.C. § 1395w-104). CMS believes that, under this requirement, Sponsors must have policies and procedures in place to identify and address fraud, waste and abuse at both the Sponsor and the third party levels in the delivery of prescription drugs through the Medicare benefit.

Furthermore, not all Sponsors have SIUs in place, nor does this chapter intend to imply that Sponsors that do not have SIUs should develop them. Instead, since the regulations placed the requirement for Sponsors to have a comprehensive fraud and abuse program within the compliance plan requirements, this Chapter provides guidance to Sponsors on how to incorporate a comprehensive fraud, waste and abuse program within their compliance plans. To the extent that a Sponsor has an existing fraud, waste and abuse program that is operated through its SIU, the Sponsor should make certain that the SIU and compliance department work closely together to ensure that the Medicare Prescription Drug benefit is reasonably protected from fraudulent, abusive and wasteful schemes throughout the administration and delivery of prescription drugs.

Additionally, the guidance provided in this chapter should not be misconstrued to mean that Sponsors should undertake law enforcement activities. Rather, Sponsors should implement effective fraud, waste and abuse programs, consistent with industry standards, to detect problems, make referrals to CMS or the appropriate CMS contractor for further investigation and follow-up, and undertake corrective action. The reporting of potential fraud to CMS and/or its designee is an important mechanism for protecting Medicare beneficiaries from harm and the Medicare Trust Fund from fraud, waste and abuse. While self-reporting of potential fraud is voluntary (42 C.F.R. § 423.504(b)(4)(vi)(H)). CMS believes that self-reporting of fraud, waste and abuse is a critical element to an effective program to control fraud, waste and abuse.

Finally, it should be noted that recommendations made in this chapter are reflected by the use of the term "should," whereas statutory or regulatory program requirements are reflected by the use of the term "shall" or "must."

30 - CMS' Use of MEDICs to Detect Fraud, Waste and Abuse

CMS has contracted with private organizations, called Medicare Drug Integrity Contractors (MEDICs). The following table describes the various activities MEDICs may perform as detailed in the Umbrella Statement of Work to prevent, detect, and audit fraud and abuse of the Part D benefit. This table is not exhaustive.

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Exhibit 1: MEDIC Responsibility and Activity Summary

| Responsibility | MEDIC Activity |
|-----------------------|--|
| Prevent | <ul style="list-style-type: none"> • Review bids for participation in the prescription drug program. • Review the fraud and abuse components of compliance plans. • Assist CMS in developing a list of entities that may require future monitoring based upon past history. • Use established or self-developed data systems to efficiently and proactively evaluate inappropriate activity that may be present in the Part D benefit. • Educate entities about potential prescription drug fraud, waste and abuse. • Facilitate intermediate sanctions as appropriate. |
| Detect | <ul style="list-style-type: none"> • Conduct thorough reviews and audits of participating entities as necessary (announced and/or unannounced/targeted). (See below for specific types of audits that may be conducted.) • Conduct complaint investigations. • Conduct preliminary investigations into entities that may be conducting fraudulent prescription drug benefit enrollment, eligibility determination, and benefit distribution. • Investigate aberrant behavior identified, and develop and refer such cases to the appropriate law enforcement agency and/or, take administrative action as necessary, when appropriate. • Perform data analysis to detect outliers that may indicate potential fraud, waste and abuse. • Identify potential overpayments. • Provide support to law enforcement agencies for investigations of potential fraud and abuse, including investigations for which an initial referral to law enforcement did not originate from the MEDIC or another CMS contractor. |
| Audit | <ul style="list-style-type: none"> • Perform one-third audits of the following information: <ul style="list-style-type: none"> ○ Bids as the data relates to Medicare utilization and costs. ○ Enhanced alternative cost sharing as the data relates to Medicare utilization and costs. ○ Reinsurance costs. ○ Risk corridor costs. ○ Low-income subsidy payments. ○ Direct subsidy payments. ○ Federal reinsurance subsidies. ○ Risk corridor payments. ○ Subsidized coverage for qualifying low-income individuals. ○ Administrative cost and its allocation. ○ Rebates. ○ Formulary. ○ Claims data. ○ TrOOP data. ○ Allocation of costs between PDPs and MA. ○ Established co-pays correctly given and calculated. • Perform other type of audits including: <ul style="list-style-type: none"> ○ Fraud and abuse compliance plan audit. ○ Beneficiary protection audit. ○ Pharmacy and Therapeutic Committee audit. ○ Medicare Advantage audit. ○ Audit of Employer Part D Plans. ○ Audit of Sponsor oversight of its contractors. ○ Audit of actuarial equivalence attestation. ○ Audit of creditable coverage disclosures. |

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MEDICs assist in the management of CMS' audit, oversight, and anti-fraud and abuse efforts in the Part D benefit (CMS RFP CMS-2006-0017, Medicare Prescription Drug Benefit (Part D), Medicare Drug Integrity Contractor. May 25, 2005). Some of the main functions of the MEDIC include identifying and investigating potential Part D fraud and abuse, developing potential Part D fraud or abuse cases for referral to law enforcement agencies, acting as a liaison to law enforcement, and serving as an auditor of Sponsor and subcontractor Part D operations. The MEDIC Umbrella Statement of Work (SOW) is archived at www.fbo.gov, under REFCMS-2005-0017A and BI-Part D-Notice. Future task orders released under this umbrella SOW will also be released through this website. CMS will release future information regarding Sponsors' expectations and responsibilities regarding interactions with the MEDICs when task orders are awarded.

40 - Part D Sponsor Accountability and Oversight

The regulations governing the Part D benefit explicitly define the major entities with which a Sponsor may contract. While it may be common practice for Sponsors to enter into contracts with third parties to perform certain functions that would otherwise be the responsibility of the Sponsor, the Sponsor maintains **ultimate responsibility** for fulfilling the terms and conditions as set out in the contract with CMS. To that end, Sponsors will be held liable for the failure to meet contractual requisites performed by first tier entities, downstream entities, and related entities working on their behalf to meet those contractual requisites (42 C.F.R. § 423.505(i)). Additionally, where a Sponsor delegates any of its activities or responsibilities to any related entity, contractor, subcontractor or pharmacy, the written arrangements must either provide for revocation of the delegation activities or specify other remedies in instances when CMS or the Sponsor determine that the parties have not performed satisfactorily (42 C.F.R. § 423.505(i)(4)(ii)). First tier entities, downstream entities, and related entities may also be subject to any applicable civil and criminal laws for fraud perpetrated in the delivery of the Part D benefit, such as the False Claims Act or the Anti-Kickback statute. The Part D regulations establish several definitions relating to entities that may contract with the Sponsor (42 C.F.R. § 423.501). Terms that are used throughout the Subpart K of the final Medicare prescription drug regulations include: (1) first tier entity; (2) downstream entity; (3) related entity; and (4) contractor (42 C.F.R. § 423 Subpart K).

First Tier Entity

The term first tier entity means any party that enters into a written arrangement acceptable to CMS with a Sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D (42 C.F.R. § 423.501). In most cases, this will be pharmacy benefit managers (PBMs).

Downstream Entity

The term downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Sponsor and a first tier entity. These written arrangements continue down to the level of ultimate provider of both health and administrative services (42 C.F.R. § 423.501).

An example of these relationships would be if a Sponsor enters into a contract with a pharmacy benefit manager (PBM). In this scenario, the PBM would be the first tier entity. The PBM then enters into a contract with various pharmacies. Those pharmacies

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would then be considered downstream entities. If pharmacies enter into a contract with several pharmacists to staff its pharmacy, those pharmacists would also be considered downstream entities.

Related Entity

The term related entity means any entity that is related to the Sponsor by common ownership or control and:

1. Performs some of the Sponsor's management functions under contract or delegation;
2. Furnishes services to Medicare enrollees under an oral or written agreement; or
3. Leases real property or sells materials to the Sponsor at a cost of more than \$2,500 during a contract period (42 C.F.R. § 423.501).

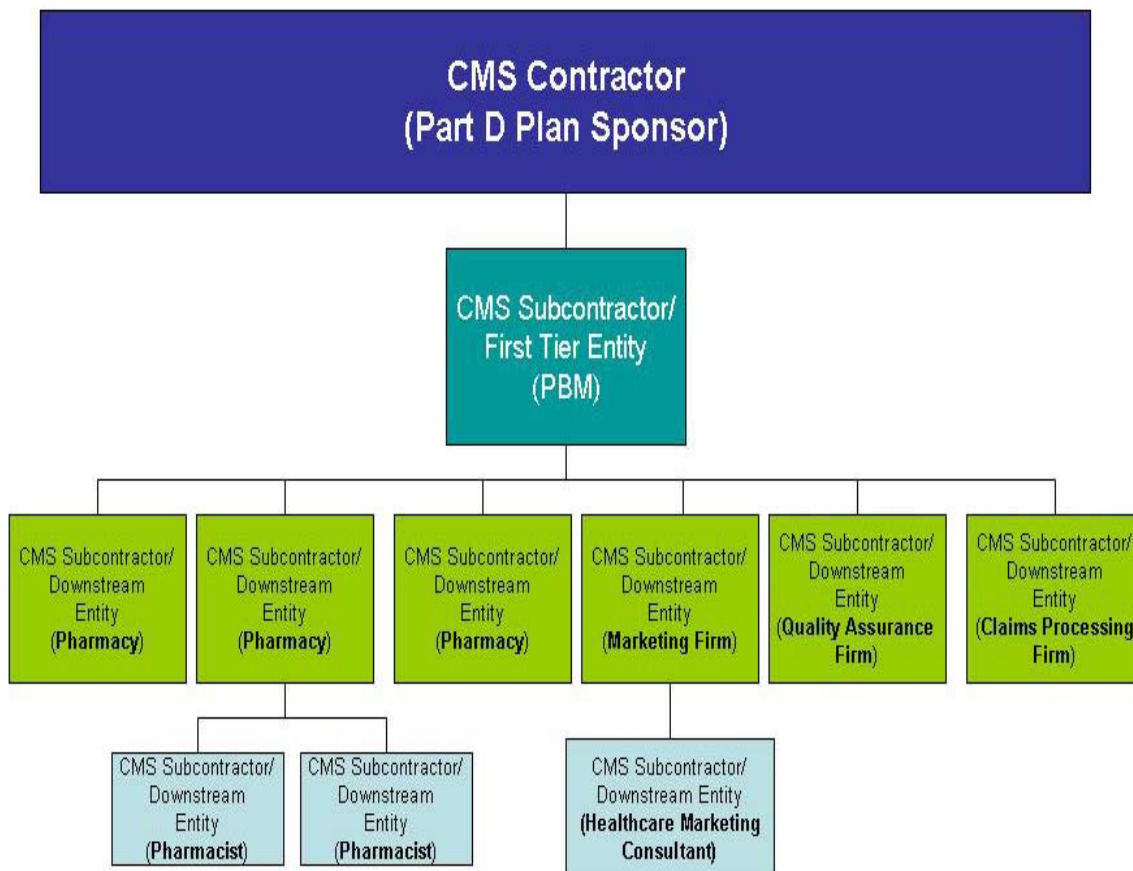
An example of a related entity would be one where a Sponsor is the parent company of its own in-house PBM (Under this scenario, the PBM would also be considered a first tier entity).

Contractor

In this Chapter, a contractor is any entity or individual that directly contracts with CMS to provide items or services, or perform tasks related to the Part D Program. Therefore, types of contractors include Part D Sponsors and Medicare Prescription Drug Integrity Contactors (MEDICs).

The following exhibit illustrates the various stakeholders involved in the prescription drug benefit and potential existing relationships.

Exhibit 2: Stakeholder Relationship Flow Chart



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Related Entities that perform Part D functions on behalf of the Sponsor (PBM, marketing, claims processing, etc.) would be either first tier entities or downstream entities under this configuration.

The regulations set forth several rules guiding Part D Sponsors in the execution of contracts with third parties (such as related entities, first tier entities, and downstream entities) for the purpose of distributing some of its Part D benefit responsibilities arising out of the Sponsor's contract with CMS. Contracts of this nature must contain specific provisions including, but not limited to, inspections, enrollee protection, Sponsor accountability, delegation, and record retention (42 C.F.R. § 423.505(e)(2); §505(i); §505(j)).

Preemption of State Laws

While Sponsors, first tier entities, downstream entities, and related entities are required to comply with applicable state laws, it is noted that certain state laws and regulations, for example, some state marketing laws regarding false or deceptive advertising, may be superseded ("preempted") by Part D laws and regulations. The recommendation is that Sponsors contact CMS if there is a question as to whether a state law or regulation is preempted by Part D laws and regulations.

40.1 - Delegating Compliance Functions

...to First Tier Entities, Downstream Entities, and Related Entities

CMS realizes each Sponsor has a unique business model and structure and some Sponsors will subcontract certain functions that other Sponsors may choose to perform themselves. CMS further realizes that some Sponsors will rely on the expertise and operations that first tier entities, downstream entities, and related entities offer.

Sponsors have the flexibility to determine how and to what extent they will delegate their program to control fraud, waste and abuse to these entities, just as Sponsors have the flexibility to determine how and to what extent they will delegate other aspects of their contractual requirements.

To the extent that any compliance functions are delegated to first tier entities, downstream entities, and related entities, Sponsors are ultimately responsible for complying with all statutory, regulatory and other requirements. To ensure proper oversight of the Sponsor's compliance program and efforts, however, the Part D Compliance Officer and compliance committee functions may not be delegated or subcontracted (See 2007 MA and PDP Call Letters). The Part D Compliance Officer, in working with the compliance committee, should develop processes and procedures to promote and ensure that any first tier entities, downstream entities, or related entities are in compliance with all applicable laws, rules and regulations with respect to any Part D delegated responsibilities.

40.2 - Contracts Executed Between Sponsors

...and First Tier Entities, Downstream Entities, and Related Entities

First tier entity, downstream entity, and related entity contracts that enable the Sponsor to fully implement all aspects of the Part D benefit are critical to protecting the Sponsor's interest. These contractual provisions must include requiring ongoing monitoring

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performed by, or on behalf of, the Sponsor which assess whether all first tier entities, downstream entities, and related entities are in compliance with Part D provisions (42 C.F.R. § 423.505(i)(4)(iii)).

First Tier Entity, Downstream Entity, and Related Entity Contract Revocation

Where a Sponsor delegates any of its activities or responsibilities to any first tier entity, or downstream entity, the written arrangements must either provide for revocation of the delegation activities or specify other remedies in instances when CMS or the Sponsor determine that the parties have not performed satisfactorily (42 C.F.R. § 423.505(i)(4)(ii)). Therefore, contracts with first tier entities, downstream entities, and related entities that enable the Sponsor to implement any aspect of an effective compliance plan are critical to protecting the Sponsor's interest.

Data Submission by First Tier Entities, Downstream Entities, and Related Entities

Sponsors are responsible for all data submitted to CMS, including data generated and/or submitted by related entities, first tier entities, and downstream entities (42 C.F.R. § 423.505(k)). CMS requires that any related entity, contractor, or subcontractor that generates claims data on behalf of a Sponsor certify to CMS the accuracy, completeness, and truthfulness of that data, and acknowledge that the data will be used for the purposes of obtaining Federal reimbursement (42 C.F.R. § 423.505(k)(3)). Sponsors are responsible for exercising oversight of Part D data generated or submitted by first tier entities, downstream entities, and related entities to ensure the accuracy of that data so that the Sponsor receives appropriate payments.

50 -The Basics of a Program to Control Fraud, Waste and Abuse

This section details the elements of a comprehensive program to detect, correct and prevent fraud, waste and abuse in the Part D benefit.

50.1 - Benefits of an Effective Program

...to Detect, Prevent and Control Fraud, Waste and Abuse

Section 1860D-4(c)(1)(D) of the Act requires Part D Plans to have in place a program to control fraud, waste and abuse (42 U.S.C. § 1395w-104). In an effort to consolidate the various compliance requirements in the Part D Voluntary Prescription Drug Delivery Program and its implementing regulations (70 Fed. Reg. 4194, 4338 (Jan. 28, 2005)). CMS included the requirement pertaining to fraud, waste and abuse as a component of a Part D Plan Sponsor's overall compliance plan.

Having a fraud, waste and abuse program in place will benefit CMS, Sponsors, and Medicare beneficiaries because it will re-target Medicare dollars to appropriate uses of Part D monies. Sponsors must comply with the compliance plan requirements set forth in the regulation in order to develop an efficient and effective program that detects and prevents fraud, waste and abuse in their Part D Plans (42 C.F.R. § 423.504(b)(4)(vi)). This chapter provides additional guidance to assist Sponsors in fulfilling the statutory and regulatory requirement to develop a comprehensive Part D fraud, waste and abuse program (42 U.S.C. § 1395w-104; 42 C.F.R. § 423.504(b)(4)(vi)(H)). Suggestions in this chapter will help Sponsors develop the fraud, waste and abuse component of the compliance plan based on the unique structure of the prescription drug benefit. These recommendations provide a road map to assist Sponsors in developing and

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implementing an effective fraud, waste and abuse program to protect their plans and the Medicare Trust Fund from fraud, waste and abuse.

Sponsors maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS (42 C.F.R. § 423.505(i)(1)). To that end, Sponsors are charged with oversight and management of the Part D benefit to ensure that beneficiaries receive the highest quality of care they are entitled to under the benefit, while at the same time protecting the integrity of Medicare funds. Therefore, it is beneficial for Sponsors to prepare, implement, and monitor all the compliance plan requirements to promote and ensure compliance with the regulations and to protect their contractual standing with CMS. Such actions should assist Sponsors in their efforts to comply with applicable laws, thus reducing their potential for enforcement action.

Sponsors may implement a program to detect, prevent and control fraud, waste and abuse in one of two ways:

1. A fraud, waste and abuse program that considers the methods described in this chapter and incorporates them into the appropriate components of a Sponsor's existing structure;

or

2. Fraud, waste or abuse provisions can be integrated into each of the elements of the Sponsor's existing compliance plan. (This chapter provides guidance on how to add a fraud, waste and abuse element to each component of a general compliance plan.)

While CMS regulations require Sponsors to implement a comprehensive fraud and abuse program, the adoption of the methods suggested within this chapter on how to implement a comprehensive fraud and abuse program are left to the discretion of each Sponsor. If a Sponsor chooses the first approach, the fraud, waste and abuse program should specifically address detecting, preventing and correcting fraud, waste and abuse in its Part D program taking into account the recommendations made in this chapter. Sponsors have the flexibility to determine how and to what extent they will assign or delegate the management of their program to control fraud, waste and abuse.

If a Sponsor chooses the second approach, it should apply the methods for detection, correction, and prevention of fraud, waste and abuse detailed in this chapter into the existing compliance policies, procedures, and standards of conduct written for its organization. Each Sponsor must determine which method is best based on the size, structure, and resources of its organization. Irrespective of the method a Sponsor chooses to implement its fraud, waste and abuse program, the Part D Compliance Officer should be the chief overseer of the Sponsor's Part D compliance program and efforts. Additionally, the Sponsor should be prepared to demonstrate its program upon request by CMS or its designee, e.g., the MEDIC.

We note that the Medicare Advantage (MA) regulations found at 42 C.F.R. § 422.503(b)(4)(vi) require that MA organizations have in place a compliance plan that mirrors the compliance plan requirements for Part D plan sponsors found at 42 C.F.R. § 423.504(b)(4)(vi), with the exception of the requirement to have a comprehensive program to control fraud and abuse as an element of the organizations compliance plan. Because this chapter provides guidance specifically to Sponsors on how to implement a

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comprehensive program to control fraud and abuse as required under the Part D regulations (42 C.F.R. § 423.504(b)(4)(vi)(H)), and because this chapter addresses both Sponsors that offer MA products as well as Sponsors that offer only stand alone prescription drug plans, this text does not address the similarities to the MA compliance plan regulations. The absence of these references does not mean to imply that MA organizations that offer prescription drug coverage cannot enhance their existing compliance plans that apply to their MA organizations to include provisions to detect, correct and prevent fraud, waste and abuse, as required for the Part D aspect of their business. Sponsors must consider their own organizational structures, as well as their size, scope and resources when determining the most appropriate methods for implementing a program to control fraud, waste and abuse.

It should be noted that recommendations made in this chapter are reflected by the use of the term “should,” whereas statutory or regulatory program requirements are reflected by the use of the term “shall” or “must.”

50.2 -Components of a Comprehensive Program

...to Detect, Prevent and Control Part D Fraud, Waste and Abuse as Part of the General Compliance Plan Requirements

The following represents the specific regulatory requirements of a compliance plan, as well as recommendations believed to help Sponsors in developing the fraud, waste and abuse component of the compliance program based on the unique structure of the prescription drug benefit.

50.2.1 - Written Policies and Procedures

The Part D Sponsor must have written policies, procedures and standards of conduct that articulate the Sponsor’s commitment to comply with all applicable Federal and State standards

Written policies, procedures, and standards of conduct clearly stating a Sponsor’s commitment to comply with all applicable Federal and state statutory, regulatory and other requirements related to the Medicare program are a critical component of a comprehensive program to detect, prevent and control fraud, waste and abuse. To help foster a culture of compliance within an organization, Sponsor’s senior management should communicate a strong and explicit organizational commitment to compliance standards and ethical corporate behavior. Having written standards in place with a strong commitment by senior management can help mitigate the risks associated with the Part D program (42 C.F.R. § 423.504(b)(4)(vi)(A)).

Written policies, procedures and standards of conduct should be updated as necessary to incorporate any changes in applicable laws, regulations, and other requirements. Written standards should include a code of conduct and policies and procedures as described below.

50.2.1.1 - Code of Conduct/Ethics

An effective compliance program will have a code of conduct that articulates an organization’s commitment to ethical behavior. The Sponsor’s written code of conduct for its Part D business should: (1) clearly articulate the Sponsor’s commitment to comply with all applicable statutory, regulatory, and other Part D program requirements; (2)

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delineate the Sponsor's expectations of employees and first tier entities, downstream entities, and related entities involved with the Part D business to act in an ethical and compliant manner and (3) include the ramifications of failure to comply with them. The code of conduct should encourage employees, management, and board members or other governing body members to report violations of law and policy to the Sponsor, CMS, its responsible designee (such as the MEDICs) and/or to law enforcement. The written code of conduct should specify the disciplinary actions that can be imposed for non-compliance, including oral or written warnings or reprimands, suspensions, terminations, and financial penalties.

The code of conduct should be written in a format that is easy to read and comprehend, and should be approved by the Sponsor's governing body (such as the board of directors) or a committee of the governing body. The code of conduct should be reviewed periodically and validated by senior management and by the governing body. When developing the code of conduct Sponsors should review existing codes of conduct used in the industry.

50.2.1.2 - Policies and Procedures

The Sponsor's policies and procedures should represent the organization's response to day-to-day risks to help reduce the prospect of fraudulent, wasteful and abusive activity by identifying and responding to risk areas. Because risk areas evolve and change over time, it is important for the Sponsor's policies and procedures to be reviewed and revised periodically. Examples of policies and procedures Sponsors should have in place to implement a comprehensive program to detect, prevent and control fraud, waste and abuse include but are not limited to:

- A commitment to comply with applicable statutory, regulatory and other requirements, subregulatory guidance, and contractual commitments related to the delivery of the Medicare Part D benefit, including but not limited to:
 - Federal and state False Claims Acts (31 U.S.C. §§ 3729-3733)
 - Anti-Kickback Statute (42 U.S.C. § 1320-7b(b))
 - Prohibition on inducements to beneficiaries (42 U.S.C. § 1320a-7a(a)(5))
 - Health Insurance Portability and Accountability Act (Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (codified as amended in scattered sections of 18 U.S.C. and 42 U.S.C.))
 - Other applicable criminal statutes - Examples of Title 18 U.S.C. violations include: §201, bribery; §287, false claims; §371, conspiracy to commit fraud; §669, theft of embezzlement in connection with health care; §1001, false statements; §1035, false statements relating to health care; §1341, mail fraud; §1343, wire fraud; §1347, health care fraud; §1518, obstruction of a federal health care fraud investigation; § 1956-57, money laundering. Examples of Title 21 U.S.C. offenses include violations of §331, Food Drug & Cosmetic Act; and §801-971, Controlled Substances Act.
 - Code of Federal Regulations - specifically, 42 C.F.R. § 400, 403, 411, 417, 422, 423, 1001, and 1003
 - All sub-regulatory guidance produced by CMS for Part D such as manuals, training materials, and guides
 - Applicable Civil Monetary Penalties and Exclusions
 - Applicable provisions of the Federal Food, Drug and Cosmetic Act
 - Applicable State laws

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- Contractual commitments
- Procedures for the identification of potential fraud, waste and abuse in a Sponsor's network.
- A process to conduct a timely, reasonable inquiry into potential violations of Federal and state criminal, civil, administrative laws, rules and regulations in a timely basis.
- A process to refer potential violations of applicable Federal and state criminal, civil and administrative laws, rules and regulations to the MEDIC and/or law enforcement for further investigation within a reasonable period (but not more than 60 days after a determination that a violation may have occurred).
- A process to ensure the Sponsor, its subcontractors, agents and brokers are marketing in accordance with applicable federal and state laws, including state licensing laws, and CMS policy (See e.g., CMS Marketing Guidelines For Part D Plan Sponsors)
- Procedures for responding timely to data requests by CMS, MEDICs, and law enforcement, or their designees.
- A process to identify overpayments and underpayments at any level within the Sponsor's network and properly report and repay, where applicable, such overpayments in accordance with CMS policy.
- A process to identify improper coverage determinations, services or enrollment at any level within its network and properly report and repay, where applicable, any overpayments resulting from inaccurate enrollment numbers in accordance with CMS policy.
- A process to identify any claims that were submitted for drugs that were prescribed by an excluded or deceased provider, and a process to report and properly repay any overpayments resulting from inaccurate payments in accordance with CMS policy.
- A process to ensure full disclosure to CMS upon request of all Sponsor pricing decisions for Part D items or services, related data and pricing records (42 C.F.R. §§ 423.308, 423.505(d)(2)(xii)). This policy should ensure transparency in the pricing structure to include all rebate and negotiated price discounts applicable to Part D drugs and services and hold the Sponsors and first tier entities, downstream entities, and related entities accountable for accurately reporting pricing information. Any information disclosed or obtained by CMS or its designee for program integrity activities will be kept confidential in accordance with 42 C.F.R. § 423.322(b).
- Policies and procedures for coordinating and cooperating with MEDICs, CMS, and law enforcement, including policies that fully cooperate with any audits conducted by the above-mentioned entities, or their designees and information requests from law enforcement agencies to support health oversight matters.
- Policies that emphasize confidentiality, anonymity, and non-retaliation for compliance related questions, or reports of potential non-compliance.
- Procedures for corrective actions designed to correct any underlying problems that result in Medicare Part D program violations and prevent future misconduct.
- Procedures to retain all records documenting any and all corrective actions imposed for conduct related to the administration or delivery of Part D benefits and follow-up compliance reviews for future health oversight purposes and/or referral to law enforcement, if necessary.
- Policies that ensure and document the review of the DHHS OIG and General Services Administration (GSA) exclusion lists for all new employees and at least once a year thereafter to ensure that its employees, board members, officers, and first tier entities,

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downstream entities, or related entities that assist in the administration or delivery of Part D benefits are not included on such lists.⁴⁰ If the Sponsor's employees, board members, officers, managers or first tier entities, downstream entities, or related entities are on such lists, the Sponsor's policies shall require the immediate removal of such employees, board members, or first tier entities, downstream entities, or related entities from any work related directly or indirectly on all Federal health care programs and take appropriate corrective actions (42 U.S.C. § 1320a-7).

- Implement a policy requiring all new and existing employees responsible for administering or delivering Part D benefits to immediately disclose any debarment, exclusion, or other event that makes them ineligible to perform work related directly or indirectly to Federal health care programs.
- Implement a policy that will require Sponsors to determine whether any future prospective or potential employee responsible for any aspect of administering or delivering Part D benefits is listed on an OIG or GSA exclusion, debarment, licensure or sanctions registry prior to hiring such prospective employee.
- The Sponsor should obtain certifications from first tier entities, downstream entities, and related entities that these entities will review the OIG and GSA exclusions lists upon initially hiring and annually thereafter to ensure that any employee or manager responsible for administering or delivering Part D benefits is not excluded from Federal health care programs. The Sponsor should likewise obtain certifications that if an employee of the first tier entity, downstream entity, or related entity responsible for the administration or delivery of any Part D benefits is on such lists, that employee will immediately be removed from any work related directly or indirectly to all Federal health care programs and the entity will take appropriate corrective actions.
- A process to comply with the ten-year record retention requirement as listed in the Federal Regulation and all clarifying instructions subsequently issued by CMS (C.F.R. § 423.505(d)).
- A commitment to Pharmacy & Therapeutic (P&T) Committee decisions that are made in accordance with CMS regulations and guidance (See 42 C.F.R. § 423.120(b)). In addition, the determination of clinical efficacy and the appropriateness of formulary drugs should precede and be paramount to cost considerations.
 - P&T committee members should sign and continually update conflict of interest statements that divulge their relationships to Sponsors or pharmaceutical manufacturers (42 C.F.R. § 423.120(b)(ii)).
 - The P&T committee should demonstrate a clear and transparent decision-making process when making formulary decisions.
 - The P&T committee should establish a process for reviewing exceptions and other utilization management processes. The policy should include provisions for drug utilization review (DUR) and Prior Authorizations (PA).
- Establish a process to ensure Sponsor's officers, directors and managers sign a statement, attestation or certification related to conflict of interest at time of hire and annually thereafter. This certification should state (1) that the individual has reviewed the organization's conflict of interest policy; (2) that the individual has disclosed any potential conflict of interests; and (3) that the individual has obtained management approval to work despite any conflicts or has eliminated the conflict.
 - The Sponsor should have policies, procedures and a disclosure protocol for:
 - a. Ensuring that officers, directors and managers do not have a conflict that provides a potential unfair competitive or monetary advantage as a result of the

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Sponsor performing the Medicare contract (e.g., ownership, control or contractual arrangement with a drug manufacturer creates an incentive to include a certain drug on a pharmacy; ownership, control or contractual arrangement with a first tier entity or downstream entity that would create an incentive to use that entity, etc.).

- b. Ensuring that the Sponsor's judgment is not biased or in some way compromised (e.g., Sponsor's formulary decisions and/or choice of contractors are not determined by ownership, control or inappropriate contractual agreement).
- c. Ensuring that ownership, control, or contractual arrangements between third-parties and the Sponsor or the Sponsor's directors, officers, managers or employees do not create a conflict;
- d. Designating a system for employees, officers, directors and managers who are seeking employment from health care providers, health plans or other Sponsors to determine if this outside employment would create a conflict;
- e. Designating a system for employees and others to bring potential conflicts to the attention of an appropriate individual;
- f. Ensuring that conflicts do not arise because of a Sponsor's access to proprietary data as a result of its Medicare responsibilities;
- g. Ensuring that a Sponsor's relationships with its vendors, suppliers, first tier entities, downstream entities, or related entities do not violate the Anti-Kickback Act and/or other applicable federal and state laws or regulations; and
- h. Ensuring that all CMS reporting requirements for potential conflicts and appropriate lobbying disclosure requirements are satisfied.
- o The Sponsor should obtain certifications from first tier entities, downstream entities, and related entities that these entities will require its managers, officers and directors responsible for the administration or delivery of Part D benefits to sign a conflict of interest statement, attestation, or certification at the time of hire and annually thereafter certifying that the manager, officer or director is free from any conflict of interest in administering or delivering Part D benefits.

50.2.1.3 - Distribution of Code of Conduct and Policies and Procedures

The Code of Conduct and the applicable policies and procedures should be made available to Sponsor's employees at time of hire, when the standards are updated, and annually thereafter. As a condition of employment, Sponsor's employees should certify that they have received, read, and will comply with all written standards of conduct. Sponsors should also encourage first tier entities, downstream entities, and related entities to adopt and follow a code of conduct particular to their own organization that reflects a commitment to detecting, preventing and correcting fraud, waste and abuse in the administration or delivery of Part D benefits. Furthermore, Sponsors are encouraged to share their code of conduct with first tier entities, downstream entities, and related entities upon request in order to relay the Sponsor's own commitment and policies and procedures aimed at preventing, detecting and preventing fraud, waste and abuse in Medicare Part D.

50.2.2 - Compliance Officer and Committee

The Part D Sponsor must designate a compliance officer and compliance committee that is accountable to senior management

This section contains guidelines that Sponsors should follow with regard to the structure, roles, and functions of their compliance officer and compliance committee.

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Irrespective of the method in which a Sponsor chooses to prevent, detect, and reduce fraud, waste and abuse, Sponsors must have a compliance officer and compliance committee in place and this function may not be subcontracted (42 C.F.R. § 423.504(b)(4)(vi)(B)) (See Medicare Advantage and Prescription Drug Plan 2007 Call Letters).

50.2.2.1 - Compliance Officer

Sponsors must have a Compliance Officer in place (42 CFR § 423.504(b)(4)(vi)(B)). CMS recommends that Sponsors dedicate a full-time employee to oversee the compliance program and operations for the Medicare prescription drug benefit (hereinafter referred to as the “the Part D Compliance Officer”). The Part D Compliance Officer may be the same individual as the corporate Compliance Officer, however CMS strongly recommends that the two positions be staffed independently. Sponsors should assess the scope of the existing Compliance Officer’s responsibilities, the size of the organization and the organization’s resources when determining whether the corporate Compliance Officer can effectively implement the Part D compliance program or whether the organization should assign a separate individual to serve as the Part D Compliance Officer.

The Part D Compliance Officer will be responsible for developing, operating, and monitoring the fraud, waste and abuse program and should have the authority to report directly to the corporate Compliance Officer (if separate from the Part D Compliance Officer), the board of directors, and the president and/or the CEO. Sponsors must ensure the Part D Compliance Officer does not hold other responsibilities that could lead to self-policing of his/her activities (e.g., the Part D Compliance Officer should not also be or be subordinate to the chief financial officer (CFO)).

Sponsors should state in the Part D Compliance Officer’s position description duties that the Compliance Officer is responsible for ensuring compliance with the Medicare Part D Program requirements. To the extent that any of the duties of the Part D Compliance Officer are delegated, it is important the Part D Compliance Officer maintain appropriate oversight of those duties he or she delegated. Examples of duties that the Part D Compliance Officer should be responsible for include but are not limited to:

- Developing and monitoring the implementation and compliance with Part D related policies and procedures through the creation and implementation of a workplan as discussed in Section 50.2.6.
- Developing an organizational chart that depicts the reporting relationship between the Part D Compliance Officer and compliance committee.
- Reporting, at least on a quarterly basis, or more frequently as necessary, to the Sponsor’s Corporate Compliance Officer, board of directors, president and/or CEO, and compliance committee, on the status of the Sponsor’s compliance program implementation, the identification and resolution of potential or actual instances of noncompliance, and the Sponsor’s oversight and audit activities.
- Creating and coordinating, or appropriately delegating, educational training programs to ensure that the Sponsor’s officers, directors, managers, employees, and other individuals working on the Part D program are knowledgeable of the Sponsor’s compliance program; its written standards of conduct, policies, and procedures; and the applicable statutory, regulatory, and other requirements.

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- Ensuring that first tier entities, downstream entities, and related entities, particularly those involved in sales and marketing activities, are aware of and follow the requirements for Medicare Part D sales and marketing activities (See Part D Plan Marketing Guidelines).
- Briefing the compliance committee and governing body on the status of compliance training.
- Developing and implementing methods and programs that encourage managers and employees to report suspected fraud and other misconduct without fear of retaliation.
- Maintaining the compliance reporting mechanism and closely coordinating with the internal audit department and the SIU, where applicable.
- Responding to reports of potential instances of Part D fraud, waste or abuse, including the coordination of internal investigations and the development of appropriate corrective or disciplinary actions, if necessary. To that end, the Part D Compliance Officer should have the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and execute any resulting corrective action (e.g., making necessary improvements to policies and practices and taking appropriate disciplinary action).
- Coordinating personnel issues with the Sponsor's Human Resources office (or its equivalent) to ensure that the DHHS OIG and GSA exclusion lists have been checked with respect to all employees, officers, directors and managers as well as first tier entities, downstream entities, and related entities are not included on such lists.
- Reporting any potential fraud or misconduct related to the Part D program to CMS, its designee and/or law enforcement in accordance with Section 50.2.8.2 of this Chapter.
- Maintaining documentation, for each report of potential fraud, waste or abuse received through any of the reporting methods (i.e. hotline, mail, in-person), which describes the initial report of non-compliance, the investigation, the results of the investigation, and all corrective and/or disciplinary action(s) taken as a result of the investigation as well as the respective dates when each of these events and/or actions occurred and the names and contact information for the person(s) who took and documented these actions.
- Overseeing the development and monitoring the implementation of corrective action plans.
- Coordinating potential fraud investigations/referrals with the SIU, where applicable, and the appropriate MEDIC and facilitate any documentation or procedural requests that the MEDIC makes of the Part D plan. Similarly, the Part D Compliance Officer should collaborate with other Sponsors, state Medicaid programs, Medicaid Fraud Control Units (MCFUs), commercial payers, and other organizations when a fraud, waste or abuse issue is discovered to involve multiple parties.
- The Part D compliance officer should have the authority to:
 - a. Report directly to the Board of Directors.
 - b. Interview or delegate the responsibility to interview the Sponsor's employees and other relevant individuals.
 - c. Review and retain company contracts and other documents pertinent to the Part D program.
 - d. Review or delegate the responsibility to review the submission of data to CMS to ensure that it is accurate and in compliance with CMS reporting requirements.
 - e. Seek advice from legal counsel.
 - f. Report misconduct to CMS, its designee and/or law enforcement.

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- g. Conduct and direct internal audits and investigations of any first tier entities, downstream entities, or related entities.

50.2.2.2 - Compliance Committee

Sponsors must have a compliance committee in place (42 CFR § 423.504(b)(4)(vi)(B)). The governing body of the Sponsor shall establish a compliance committee that is overseen by the Part D Compliance Officer, advises the Part D Compliance Officer and assists in implementation of the Part D compliance program. This compliance committee may operate within the structure of the existing compliance committee, or may operate as a separate and distinct committee. Examples of duties that the compliance committee should be responsible for include but are not limited to:

- Meet at least on a quarterly basis, or more frequently as necessary.
- Develop strategies to promote compliance and the detection of any potential violations.
- Ensuring that training and education are appropriately completed.
- Assist with the creation and implementation of the monitoring and auditing workplan.
- Assist in the creation of effective corrective action plans and ensure that they are implemented and monitored.
- Develop innovative ways to implement appropriate corrective and preventive action.
- Oversee a system of internal controls to carry out the organization's standards as part of its daily operations.
- Support the Part D Compliance Officer's needs for sufficient staff and resources to carry out his or her duties.
- Ensure the Sponsor has appropriate, up-to-date compliance policies and procedures.
- Ensure the Sponsor has a system for employees, first tier entities, downstream entities, and related entities to ask compliance questions, and report potential instances of fraud, waste or abuse confidentially or anonymously (if desired) without fear of retaliation.
- Review and address reports of monitoring and auditing of areas in which the Sponsor is at risk of fraud, waste or abuse and ensuring that corrective action plans are implemented and monitored.
- Provide regular and ad hoc reports on the status of compliance with recommendations to the Sponsor's Board of Directors.

Members of the compliance committee should include individuals with a variety of backgrounds, and reflect the size of the organization and the organization's resources. For example, Sponsors should consider including members of senior management (e.g., Chief Financial Officer, Chief Operating Officer), pharmacists, registered nurses, nationally certified pharmacy technicians, and auditors that perform medical review on the compliance committee to the extent that their organization is sufficiently staffed and where a large compliance committee would reflect the size and scope of the organization. Other staff members might include personnel experienced in legal issues, staff/ manager from various departments within the organization who are in the best position to understand vulnerabilities within their respective areas of expertise, and statistical analysts.

50.2.3 - Training and Education

The Part D Sponsor must provide effective training and education between the Part D Compliance Officer and organization employees, subcontractors, agents, and directors who are involved in the Part D benefit.

This section provides recommendations on how Sponsors can develop training and education programs that will help them comply with the regulations as well as assist them in fraud, waste and abuse prevention efforts. Compliance training should address pertinent laws related to fraud and abuse (e.g., Anti-Kickback Statute, False Claims Act, etc.) and include a discussion of Part D vulnerabilities as identified by the Sponsor, CMS, the OIG, the Department of Justice, and other organizations (42 C.F.R. § 423.504(b)(4)(vi)(C)).

All persons involved with the Sponsor's administration or delivery of the Part D benefit should receive general compliance training. To the extent that it is feasible and reasonable, first tier entity, downstream entity, and related entity staff should be permitted to attend the Sponsor's training or agree to conduct their own Part D compliance training in accordance with the guidance provided below.

50.2.3.1 - General Compliance Training

All Sponsor personnel responsible for the administration or delivery of Part D benefits should receive general compliance training upon initial hiring, upon the initial adoption of a compliance program, and annually thereafter as a condition of employment. Sponsors should maintain records of the time, attendance, topic and results of training. Sponsors should also consider requiring that any first tier entities, downstream entities, and related entities with any Part D responsibilities on behalf of the Sponsor to have their own training, or where there are sufficient organizational similarities, the Sponsor may choose to make its training programs available to these entities.

The governing body, compliance committee members, officers and senior management should receive training on the structure and operation of the compliance program on an annual basis. Supervisors should be trained to respond appropriately to compliance inquiries and reports of potential non-compliance. Training should include: treating each question/ report confidentially; non-retaliation against any employee asking a question or making a report; and knowing when to refer the incident to the compliance officer. The following are examples of topics the general compliance training program should communicate:

- A description of the compliance program, including a review of compliance policies and procedures, the code of conduct, and the organization's commitment to business ethics and compliance with all statutory, regulatory, and Medicare program requirements.
- Overview of system or process to ask compliance questions, request compliance clarification or report potential non-compliance. Training should emphasize confidentiality, anonymity, and non-retaliation for compliance related questions, or reports of potential non-compliance.
- Review of the disciplinary guidelines for non-compliant or fraudulent behavior which results in mandatory retraining and may result in disciplinary action, including possible termination when such behavior is serious or repeated or when knowledge of a possible violation is not reported.

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- Attendance and participation in formal training programs as a condition of continued employment, and a criterion to be included in employee evaluations.
- Review of policies related to contracting with the government, such as the laws addressing fraud and abuse or gifts and gratuities for Government employees.
- Review of potential conflicts of interest and the Sponsor's disclosure/attestation system.
- Overview of HIPAA, the CMS Data Use Agreement, and the importance of maintaining the confidentiality of Personal Health Information.
- Overview of the monitoring and auditing workplan of the organization.

50.2.3.2 - Specialized Compliance Training

Employees that have specific responsibilities in Medicare Part D business areas should receive specialized training on issues posing compliance risks based on their job function (e.g., pharmacist, statistician, etc.) upon initial hire, when requirements change, or when an employee works in an area previously found to be non-compliant with program requirements or implicated in past misconduct, and at least annually thereafter as a condition of employment. Specialized training content may be developed by the Sponsor, or employees may attend professional education courses that help meet this objective.

Sponsors should require that any first tier entities, downstream entities, and related entities with any Part D responsibilities on behalf of the Sponsor to have their own specialized compliance training, or where there are sufficient organizational similarities, the Sponsor may choose to make its training programs available to these entities. Examples of specialized training for Sponsor employees, directors and agents include, but are not limited to training for those involved in:

- Marketing the prescription drug benefit to Medicare beneficiaries.
- Managing or administering the exceptions and appeals process.
- Calculating TrOOP.
- Making negotiated prices available to beneficiaries.
- Submitting the payment bid to CMS.
- Payment reconciliation.
- Submitting Part D data to CMS.
- Negotiating rebate agreements with Pharmaceutical Manufacturers, wholesalers, and other suppliers of Part D drugs. This recommendation is provided to suggest that those individuals responsible for negotiating rebate agreements or price concessions on behalf of the Sponsor are aware of the particular responsibilities and vulnerabilities associated with such negotiations. CMS in no way is attempting to interfere with the competitive model that underlies Part D, in violation of Section 1860D-11(i) of the Act. Rather, CMS is attempting to protect the processes by which the competitive model operates.
- Negotiating pharmacy network agreements.
- Administering the compliance program and operations, i.e., the Part D Compliance Officer and his/her staff.
- Conducting administrative activities necessary for the operation of the Part D benefit.
- Managing employer group plans.
- Security and authentication instructions involved in Health Information Technology.

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Because Sponsors maintain ultimate responsibility over the administration of the Part D benefit, where resources are available, Sponsors should consider offering training and education to their first tier entities, downstream entities, and related entities. In the case of chain pharmacies and large PBMs, Sponsor-held training and education may supplement existing training programs. This may include web-based tools, intranet sites and videotaped presentations. Independent pharmacies, which in general have fewer resources, may appreciate the access that a training program affords to critical Part D information.

Some first tier entities, downstream entities and related entities may be providing services to multiple Sponsors, and it may become cumbersome for them to attend training at the various Sponsor locations. Rather, first tier entities and downstream entities that provide services to multiple Sponsors may prefer to host their own Part D training that meets CMS training recommendations.

Because risk areas evolve and change over time, general and specialized compliance training should be reviewed and revised as needed but at least annually. Additionally, Sponsors should retain adequate records of their training of employees, including attendance logs and material distributed at training sessions. Sponsor employees should certify at least annually that they have received general and specialized compliance training. These materials should be made available to CMS upon request.

50.2.3.3 - Methods of Training

The Sponsor should have in place a mechanism for the Part D Compliance Officer to continually disseminate the compliance message in new and innovative ways. This is not to suggest that Sponsors who have developed effective methods for communicating the organization's compliance message abandon those successful methods. A variety of teaching methods may suit the needs of different organizations, depending on the size of the workforce and scale of training. Training can be conducted interactively led by expert facilitators, via web-based tools and Intranet sites, live or videotaped presentations, written materials, or a combination of these techniques. Other methods include lecturing or "talking head" videos. Such methods of training are best reserved for introductory training that explains the organization's commitment to compliance. The best training and education approach is to engage employees in substantive discussion to reinforce the organization's compliance with applicable laws, regulations, standards, and principles. In addition, training should be designed to ensure that employees understand what is expected of them. Sponsors should consider administering tests or quizzes during training sessions to ensure that employees understand the compliance goals of the organization. In addition, training could be incorporated into the organization's orientation of new employees.

50.2.4 - Effective Lines of Communication

The Part D Sponsor must have effective lines of communication between the Compliance Officer and the organization's employees, contractors, agents, directors, and members of the compliance committee.

50.2.4.1 - Effective Lines of Communication Between the Compliance Officer, Employees, Contractors, Agents, Directors, and Compliance Committee

Sponsors should have a system in place to receive, record, and respond to compliance questions, or reports of potential or actual non-compliance from employees, contractors, agents and directors while maintaining confidentiality, allowing anonymity if desired (e.g. through telephone hotlines or mail drops), and ensuring non-retaliation against callers. Sponsors must establish a system that fosters effective lines of communication between the Compliance Officer and the organization's employees, subcontractors, agents, directors, and members of the compliance committee regarding how to report compliance concerns and suspected or actual misconduct. (42 C.F.R. § 423.504(b)(4)(vi)(D)). The Sponsor should also establish effective lines of communication with its enrollees. An organization that fosters open communication can be highly effective at identifying, reporting and mitigating misconduct under the Part D benefit.

It is crucial that a confidential or anonymous reporting mechanism be in place for those who may be uncomfortable reporting concerns directly to a supervisor or to the Part D Compliance Officer. Sponsors should adopt, routinely publicize, and enforce a zero-tolerance policy for retaliation or retribution against any employee or subcontractor who reports suspected misconduct. Employees and subcontractors should be notified that they are protected from retaliation under 31 U.S.C. § 3730(h) for False Claims Act complaints, as well as any other applicable anti-retaliation protections.

The Sponsor's written standards should require all employees, contractors, agents and directors to report compliance concerns and suspected or actual misconduct. These concerns and risks should be captured via independent mechanisms, which may include hotlines, suggestion boxes, employee exit interviews, e-mails, and other forums that promote information exchange. Such a mechanism shall be made available and easily accessible to the Sponsor's employees, contractors, agents and directors.

50.2.4.2 - Establishing a Mechanism to Field Compliance Questions and Concerns from Employees First Tier Entities, Downstream Entities and Related Entities

Although Sponsors can develop any mechanism to field compliance questions and concerns, one of the most common methods is through the establishment of a hotline. Hotlines may be developed and maintained internally or the Sponsor may employ an independent contractor to operate the hotline. Regardless of the method used to field such reports, i.e., hotline or other mechanism, Sponsors should make it easily available for employees, contractors, agents and directors to access. For example, Sponsors could develop hotline posters with an easy to remember hotline phone number that is accessible 24 hours a day. Routine reminders would also be helpful so employees and subcontractors remember that this reporting mechanism exists. Hotline numbers should be prominently posted and available to all employees and contractors throughout the organization.

After employees, contractors, agents or directors report a suspected compliance issue, Sponsors should provide the complainant with information about a timely response, confidentiality, and provision of progress reports. Sponsors should establish procedures for responding to reports of a suspected compliance issues in a timely manner, assuring

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the complainant that the reports will be handled in a confidential manner. Any information provided to the complainant regarding the progress of the investigation can be expected to differ depending upon the particular facts and circumstances of the issue.

Sponsors should implement prompt follow-up

Investigation procedures in response to hotline inquiries and other complaints.

The effectiveness of hotlines relies on several criteria, namely confidentiality, accessibility, intake, and follow-up. Follow-up investigations stemming from hotline inquiries and other complaints should be initiated within 2 weeks of receiving the complaint. Reporting potential fraud, waste or abuse can be highly sensitive. Sponsors should establish a process to document and track reported concerns and issues, including the status of related investigations and corrective actions. Such a process will help improve the Sponsor's efficacy in resolving reports and preventing or correcting ongoing non-compliance. Sponsors may want to analyze the reports to identify patterns of possible misconduct by certain departments within the plan, or by pharmacy, PBMs, providers, and beneficiaries.

Screening Enrollee Complaints

Sponsors must follow the grievance procedures outlined in 42 C.F.R. Subpart M, and the procedures outlined in the Medicare Part D Reporting Requirements (See "Part D Enrollee Grievances, Coverage Determinations and Appeals"). Sponsors must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Sponsor or any other entity or individual through whom the Sponsor provides covered benefits under any Part D plan it offers (42 C.F.R. § 423.564(a)). The regulations define grievance as any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities or behavior of a Part D plan Sponsor, regardless of whether remedial action is requested (42 C.F.R. § 423.560).

In order to adequately receive such complaints, address the concerns, and track records on these complaints (42 C.F.R. § 423.564(g)), Sponsors should have a complaint tracking system including, at a minimum, a call center with an explicit process for handling customer complaints for beneficiaries, and should make this log available to CMS or its designee, e.g. the MEDIC, upon request. Such complaints may come through the customer service phone number, which should not be the same as the employee hotline number described above. CMS expects that potential fraud complaints will be referred to the MEDIC in accordance with the procedures set forth in 50.2.8.2 of this Chapter.

Enrollee Communications and Education

Sponsors should consider various methods to educate enrollees on prescription drug fraud, waste and abuse. Such methods may include flyers, letters or pamphlets that can be included in mailings to enrollees (such as enrollment package, Explanation of Medicare Benefits ("EOB"), etc.). These communications should be available to CMS or its designee, e.g. the MEDIC, upon request.

50.2.5 - Enforcement of Standards

The Part D Sponsor must enforce standards through well-publicized disciplinary guidelines.

Enforcement of standards is an essential element of a compliance plan. Additionally, the enforcement of standards is essential to Sponsors' efforts to prevent, detect, and reduce fraud, waste and abuse. This section discusses guidelines that Sponsors should follow when enforcing standards through well-publicized disciplinary guidelines. The following topic areas are addressed in this section: (1) involvement of CEO and other senior management; (2) methods to publicize disciplinary guidelines; and (3) enforcing standards of conduct. (42 C.F.R. § 423.504(b)(4)(vi)(E)).

50.2.5.1 - Involvement of Chief Executive Officer (CEO) ...and other Senior Management

To help communicate a strong and explicit organizational commitment to compliance goals and standards, the Sponsor's governing body, CEO, chief operating officer (COO), general counsel, chief financial officer (CFO), and other senior officials should be directly involved in the development and/or review of standards for conduct. Management involvement in this process helps communicate the need for all employees to comply with the organization's standards of conduct.

50.2.5.2 - Methods to Publicize Disciplinary Guidelines

To encourage the reporting of incidents of unethical or noncompliant behavior, the Sponsor, under direction of the Part D Compliance Officer, may consider using any of the following methods to publicize disciplinary guidelines:

- Newsletters which explain compliance issues and methods.
- Include compliance guidelines as a regular topic at department staff meetings, in communications with subcontractors, and in the annual general compliance training.
- Post information about compliance issues and reporting methods to the organization's Intranet site.
- Prominently display posters, cafeteria table tents, or other such vehicles which emphasize the importance of compliance.

This information should be made available to senior management, employees, first tier entities, downstream entities, and related entities as appropriate.

The Sponsor should disseminate among its senior management and employees responsible for the administration or delivery of Part D benefits, as well as among first tier entities, downstream entities, and related entities, when appropriate, the procedures to ask compliance questions, and make reports of potential fraud, waste or abuse to the Part D Compliance Officer or to the MEDIC. The reporting procedures should include:

- A description of the various methods available to make reports or ask compliance questions.
- A description of how anonymous reports may be made and how the anonymous system will allow the reporter to provide additional information (if needed) and receive status updates on the investigation.
- A description of the Sponsor's policy on no retaliation or retribution for reports made in good faith.

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- A description of how to report potential fraud to the appropriate MEDIC, and/or to law enforcement, e.g. by displaying its toll-free number.

50.2.5.3 - Enforcing Standards of Conduct

Sponsor's guidelines should reflect clear and specific disciplinary policies, and provide the consequences of violating the organization's standards of conduct. All employees should be informed that violation of standards may result in appropriate disciplinary action, up to and including termination of employment. The Sponsor should have a provision its contract with first tier entities, downstream entities, and related entities that violations may result in termination of the contractual relationship with the Sponsor. Sponsors should also enforce standards of conduct through other practices. It is good business practice to maintain and periodically review records of discipline for compliance violations to promote consistency and fairness. Sponsors should also consistently undertake appropriate disciplinary action across the organization so that the disciplinary policy has a deterrent effect.

50.2.6 - Monitoring and Auditing

The Part D Sponsor must have procedures for effective internal monitoring and auditing. (42 C.F.R. § 423.504(b)(4)(vi)(F))

An internal monitoring and auditing program will help protect the Medicare program and beneficiaries from Part D fraud, waste and abuse and may help mitigate the Sponsor's, first tier entities, downstream entities, and related entities' liability resulting from potentially fraudulent, abusive or wasteful activities. Procedures for internal monitoring and auditing should test and confirm compliance with the Part D benefit regulations, subregulatory guidance, contractual agreements, and all applicable state and federal laws, as well as internal policies and procedures to protect against potential fraud, waste or abuse.

Sponsors should develop a monitoring and auditing workplan ("workplan") that addresses the risks associated with the Part D benefit. The Part D Compliance Officer and compliance committee are key participants in this process. Sponsors should have a system of ongoing monitoring that is reflective of its size, organization and resources and is coordinated, overseen or executed by the Part D Compliance Officer to assess performance in, at a minimum, areas identified as being at risk. The monitoring system includes the Part D Compliance Officer receiving regular reports of performance, documentation review, and updates on peripheral issues such as systems, staffing, etc. The Part D Compliance Officer should provide updates on the monitoring results to the compliance committee and senior leadership.

An audit refers to a formal review of compliance with a particular set of internal (e.g., policies and procedures) or external (e.g., laws and regulations) standards used as base measures. Monitoring activities refer to reviews that are repeated regularly during the normal course of operations. Monitoring activities may occur to ensure corrective actions are undertaken or when no specific problems have been identified to confirm ongoing compliance.

50.2.6.1 - Development of the Monitoring and Auditing Workplan

The workplan should include information regarding all the components and activities needed to perform monitoring and auditing, such as:

- (1) Internal Audit Department Requirements,
- (2) Audit Schedule and Methodology, and
- (3) Types of Auditing.

50.2.6.1.1 - Internal Audit Department

In developing the Part D workplan the Part D Compliance Officer and compliance committee should consider, to the extent one does not already exist, the creation of an internal audit department appropriate to the organization's size, scope and structure. The internal audit department should be allocated an annual budget based on the number of employees the Sponsor has dedicated to the administration of the Medicare Part D benefit, taking into account the resources necessary to complete the goals set forth in the workplan each year. Sponsors should ensure that the internal audit department staff has the appropriate skills and expertise to perform the work. For example, to the extent that resources are available, the internal audit department should include pharmacists, nurses, physicians, certified public accountants, and other highly skilled staff that have expertise in the areas under review. Additionally, Sponsors should ensure the internal audit department staff are knowledgeable of Medicare program requirements, and should provide specialized training to internal audit department staff annually. To the extent that the creation of an internal audit department is unreasonable given the Sponsor's size, scope and resources, the Sponsor should consider delegating this responsibility to a third party.

Sponsors should ensure that the internal audit department staff is independent and objective. For example, staff performing internal audits should not audit their own work. Sponsors should ensure internal audit staff has access to the relevant personnel, information, records and areas of operation under review so they can adequately perform the audits. Such access would include the operational areas at the plan level as well as the subcontractor level.

50.2.6.1.2 - Audit Schedule and Methodology

The workplan should include a schedule that includes a list of all the monitoring and auditing activities for the calendar year. Sponsors may want to organize the schedule by month or quarter. Examples of what the schedule should contain include but are not limited to:

- Responsible Internal Audit Staff Member
- Start and Completion Date
- Whether or not it will be announced or unannounced
- Whether or not it will be a desk audit or an on-site audit
- When the results will be presented to the Part D Compliance Officer and compliance committee

Sponsors should consider a combination of desk and on-site audits, including unannounced internal audits or "spot checks," when developing the schedule. While desk audits are more cost efficient and can be effective in the review of a large amount of high level data, on-site audits provide the auditor an opportunity to assess the on-site

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operations, interview staff, and gain a better understanding of the performance of the area under review.

Sponsors should produce a standard audit report that includes items such as:

- Audit Objectives
- Scope and Methodology
- Findings
 - Condition
 - Criteria
 - Cause
 - Effect
- Recommendations

In developing the types of audits to include in the workplan Sponsors should:

- Conduct a risk assessment of all program areas and rank the results according to risk.
- Determine which risk areas will most likely affect their organization and prioritize the monitoring and audit strategy accordingly. In addition to the review of risk areas present in a Part D plan, Sponsors should review risk areas associated with beneficiaries, providers, pharmacies, PBMs, wholesalers, and manufactures, as well as the Sponsors themselves.
 - Sponsors should consult resources such as this chapter, including Section 70, *Potential Risks for Fraud, Waste and Abuse*, the annual OIG workplan, and resources developed by the industry that identify high risk areas in the prescription drug benefit.
 - Among other things, Sponsors should perform regular audits of bids, pricing data, changes in drug prices, and data for determining risk adjustments and TrOOP.
 - Sponsors should separately assess the risks of their pharmacy network to assure compliance with all areas of pharmacy dispensing.
- Utilize statistical methods, when appropriate, in:
 - Randomly selecting Sponsor facilities, pharmacies, providers, claims, and other areas for review;
 - Determining appropriate sample size; and
 - Extrapolating audit findings using statistically valid methods that comply with generally accepted auditing standards to the full universe.
- Utilize statistical methods, when appropriate, in applying targeted or stratified sampling methods driven by data mining and complaint monitoring.
- Utilize special target techniques based on aberrant behavior.
- Assess compliance with internal processes and procedures.
- Examine the performance of the compliance program including review of training, the reporting mechanism (e.g. hotline log), investigation files, sanction screenings, certifications for receipt of standards of conduct, and conflict of interest disclosure/attestation.
- Conduct follow up review of areas previously found non-compliant to determine if the corrective actions taken have fully addressed the underlying problem.

Sponsors should also include in their workplan a process for responding to all monitoring and audit results. Corrective action and follow-up should be led or overseen by the Part D Compliance Officer and include actions such as the repayment of identified overpayments and making reports to MEDICs, if necessary. The Part D

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Compliance Officer should maintain a records system to track all compliance actions taken and outcomes of any follow-up reviews to evaluate the success of implementation efforts that may be provided, and provide updates on the monitoring and auditing results and corrective action to the compliance committee and senior leadership on at least a quarterly basis. When appropriate, the Sponsor should inform CMS, the MEDIC or law enforcement of aberrant findings

50.2.6.1.3 - Monitoring and Auditing

...First Tier Entities, Downstream Entities, and Related Entities

As stated in the preamble to the Title I regulations, it is recognized that Sponsors are not law enforcement entities, and it is not expected that Sponsors pursue fraudulent activities in the same manner that law enforcement would. However, just as other contractors who administer Medicare benefits are responsible for monitoring for wasteful, abusive, and fraudulent activities in their organizations, the same expectations holds true for Part D plan sponsors (70 Fed. Reg. 4194, 4339 (January 28, 2005)).

Therefore, Sponsors should develop as part of their workplan a strategy to monitor and audit first tier entities, downstream entities, and related entities involved in the administration or delivery of the drug benefit. Because Sponsors and first tier entities, downstream entities, and related entities must follow applicable state and federal laws and regulations, Sponsors must have a plan in place to monitor and audit first tier entity, downstream entity, and related entity responsibilities and activities with respect to the administration and delivery of the drug benefit. Specific data should be analyzed from first tier entities, downstream entities, and related entities as applicable and appropriate, and reviewed regularly as routine reports are collected and monitored.

Sponsors should include routine and random auditing as part of their contractual agreement with first tier entities, downstream entities, and related entities. Sponsors should include in their workplan the number of first tier entities, downstream entities, and related entities that will be audited each year, how the entities will be identified for auditing, and should make it a priority to conduct a certain number of on-site audits. Sponsors must ensure their contracts with first tier entities, downstream entities, and related entities require record retention and provide rights of access to these records to CMS or its designee (42 C.F.R. §423.505(i)(2)).

Audits should include a review of documentation such as prescriptions, invoices, pharmacy licenses, claim transaction records, signature logs, purchase records, and negotiated prices, as well as verification that network providers are in compliance with the minimum standards pharmacy practice as established by the States (42 C.F.R. § 423.153(c)(1)), and verification that network pharmacies post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request and exception if they disagree with information provided by a pharmacist (42 C.F.R. § 423.562(a)(3)). Audits should also include a review of first tier entity, downstream entity, and related entity contracts, as well as rebate, discount, and all other relevant agreements (and supporting data). Additionally, Sponsors should conduct interviews with first tier entity, downstream entity and related entity staff to gauge whether applicable Part D requirements are being followed.

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To aid in their monitoring and oversight efforts of first tier entities, downstream entities, and related entities in addition to other monitoring and auditing activities, Sponsors should generate or receive and review reports such as the following:

Payment Reports which detail the amount paid by both the Sponsor and the beneficiary, the pharmacy provider, the beneficiary and a description of the drug provided, including dosage and amount. These reports should be used to identify over and under payments, duplicate payments, timely payments, pricing aberrances, and to help verify correct pricing.

Drug Utilization Reports which identify the number of prescriptions filled by a particular enrollee and in particular numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by an enrollee. Enrollees with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports and the enrollee and their prescribing providers should be contacted and explanations for use should be received. Likewise, Drug Utilization Management reports from subcontractors may be a useful tool in identifying fraud, waste and abuse.

Prescribing Patterns by Physician Reports which identify the number of prescriptions written by a particular provider and typically focus on a class or particular type of drug such as narcotics. These reports should be generated to identify possible prescriber/provider or pharmacy fraud.

Geographic Zip Reports which identify possible doctor shopping schemes or script mills by comparing the geographic location (zip code) of the patient to the location of the provider that wrote the prescription and should include the location of the dispensing pharmacy. These reports should generate information on those enrollees who obtain multiple prescriptions from providers located more than the normal distance traveled for care (for example, 30 miles). "Normal distance" should take into account where the beneficiary resides (i.e., beneficiaries in rural areas would typically have longer trips to a doctor or pharmacy than beneficiaries living in urban areas).

In the event that first tier entities, downstream entities, and related entities perform their own audits related to the prescription drug benefit, Sponsors should seek written assurances from these entities that they have an adequate audit workplan in place. Sponsors should regularly receive these audit results with respect to their enrollees, and likewise seek assurances that corrective actions are taken by the entity when appropriate.

50.2.6.2 - Use of Data Analysis

...for Fraud, Waste and Abuse Prevention and Detection

The use of data analysis by a Sponsor is another effective tool for fraud, waste and abuse prevention and detection at the Sponsor and first tier entity, downstream entity, and related entity levels. Data analysis should include the comparison of claim information against other data (e.g., provider, drug provided, diagnoses, or beneficiaries) to identify potential errors and/or potential fraud. Data analysis typically provides an overarching view of what is happening and can help Sponsors identify trends and assist in the development of more focused audits. Data analysis should factor in the particular prescribing and dispensing practices of providers who serve a particular population (e.g., long term care providers, assisted living facilities, etc.) Plans should invest in data analysis software applications that give them the ability to analyze large amounts of data. Data analysis should:

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- Establish baseline data to enable the Sponsor to recognize unusual trends, changes in drug utilization over time, physician referral or prescription patterns, and plan formulary composition over time;
- Analyze claims data to identify potential errors, inaccurate TrOOP accounting, and provider billing practices and services that pose the greatest risk for potential fraud, waste and abuse to the Medicare program;
- Identify items or services that are being over utilized;
- Identify problem areas within the plan such as enrollment, finance, or data submission;
- Identify problem areas at the first tier entity, downstream entity, and related entity level (e.g., PBM, pharmacies, and pharmacists) and at the prescriber level; and
- Use findings to determine where there is a need for a change in policy.

Sponsors should develop indicators that will be used to identify norms, abnormalities, and individual variables that describe statistically significant time-series trends.

Examples of such statistically significant time series trends over time and in comparison to relative time periods:

- Standard deviations from the mean.
- Percent above the mean or median.
- Percent increase in charges, number of visits/services from one period to another.

50.2.6.3 - Other Monitoring and Oversight Efforts

Sponsors should consider adopting other monitoring and oversight efforts to assist in mitigating risks of fraud, waste and abuse in the delivery of the Part D benefit.

50.2.6.3.1 - Claims Processing System Recommendations

Claims processing systems can be an effective tool for plans to monitor the delivery of the prescription drug benefit. Sponsors should use claims processing systems that can be programmed to recognize various claims components and respond to each recognized component. Plans must follow instructions regarding prescriptions drug claims processing as dictated by CMS. See <http://www.cms.hhs.gov/pdps/PDClaimProc.asp> for additional information regarding requirements. Sponsors should have systems capability to establish an edit on a given provider and use that edit to automatically deny a claim or suspend payment on a claim when appropriate.

Examples of edits include but need not be limited to:

- Controls on early refills outside of long-term care settings. (See CMS Frequently Asked Question ID # 6986, “May Part D plans reject claims as “too soon” when an enrollee no longer has access to their previously filled prescription medication because they have been admitted or discharged from a long term care facility?”)
- Limits on the number of days before a refill is permitted outside of long-term care settings.
- Edits to prevent payment for statutorily excluded drugs.
- Limits on the number of times a prescription can be refilled.
- Brand name versus generic drugs.
- Number of prior authorizations.
- Real time contraindication (e.g. drug- drug interactions).
- Sex and age edits compared to the drug prescribed.
- Therapeutic edits.

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- Excessive claims for controlled substances.
- Insufficient or excessive dosage edits.
- Step therapy edits.
- Identifying drugs provided outside of the Part D benefit by Patient Assistance Programs.

System edits may be used to trend billing practices in a certain region by reviewing providers, beneficiaries, etc. within that zip code. Also, editing should be used to review how a provider is prescribing the same drug or very similar drugs by utilizing name brand versus generic and to review utilization patterns to trend the types of prescriptions being used by beneficiaries.

50.2.6.3.2 -Identifying Providers with a History of Complaints

Sponsors should maintain files on providers who have been the subject of complaints, investigations, violations, and prosecutions. This includes enrollee complaints, MEDIC investigations, OIG and/or DOJ investigations, US Attorney prosecution, and any other civil, criminal, or administrative action for violations of Federal health care program requirements. Also, Sponsors should maintain files that contain documented warnings (i.e. fraud alerts) and educational contacts, the results of previous investigations, and copies of complaints resulting in investigations. Plans are expected to comply with law enforcement, CMS and CMS' designee requests to monitor providers within their network that CMS has viewed as potentially abusive or fraudulent.

50.2.6.3.3 - Sponsors Shall Deny Claims

...for Drugs that are Prescribed by an Excluded Provider

Sponsors shall not pay for drugs prescribed or provided by a provider excluded by either the HHS OIG or GSA (See 42 C.F.R. § 1001.1901). Sponsors should review the HHS OIG and GSA exclusion lists at least once a year, and have processes in place to prevent the payment of claims for services provided by excluded providers. If a Sponsor discovers any claims that were submitted for drugs that were prescribed by an excluded provider, the Sponsor should investigate to determine whether other claims have been submitted for items prescribed by the excluded provider and report the claims to the MEDIC.

50.2.6.4 -Auditing by CMS or its Designee

CMS is required to annually audit the financial records of “at least one-third” of the Part D Sponsors offering Part D drug plans (42 U.S.C. § 1395w-112; 42 C.F.R. § 423.504(d)). Therefore when requested, Sponsors must be prepared to allow CMS to audit its financial records, including data relating to Medicare utilization and costs (42 C.F.R. § 423.504(d)). The one-third audit authority applies to all Sponsors. Examples of an organization’s financial records include but are not limited to:

- Data relating to Medicare utilization and costs.
- Reinsurance costs.
- Low-income subsidy payments.
- Risk corridor cost.
- Bid calculation.
- Rebate information.

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Sponsors must allow access to any auditor acting on behalf of the federal government or CMS to conduct an on-site audit (42 C.F.R. § 423.505(e)(3)). On-site audits may also be conducted, at the discretion of CMS, of any subcontracted entity of the Sponsor. Independent of the aforementioned authority for conducting the one-third audits described above, CMS may inspect and audit any pertinent contracts, books, documents, papers, and records of a Sponsor or its subcontractor involving transactions related to CMS' contract with the Sponsor (42 C.F.R. §§ 423.505(e)(2); 423.505(i)(2)).

On-site audits require a thorough review of required documentation. Such reviews include any information needed to determine compliance with the Part D contract and the Part D regulation, such as copies of prescriptions, invoices, pharmacy licenses, claims records, signature logs, purchase records, contracts, rebate and discount agreements, as well as, interviews of the staff. The interviews gauge whether control activities are practiced as dictated by the company's policy and applicable Part D requirements are being followed. On-site audits are based on random sampling or results of desk audits. In most cases, CMS or its designee will provide reasonable notice to the Sponsor, first tier entity, downstream entity, or related entity of the time and content of the audit. The OIG has independent authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement.

Sponsors, first tier entities, downstream entities and related entities must provide records to CMS or its designee and should cooperate in allowing them access to their facilities as requested. Failure to do so may result in a referral of the Sponsor and/or subcontractor to law enforcement and/or implementation of other corrective actions, including intermediate sanctioning in line with 42 C.F.R. Subpart O. MEDICs tasked to conduct audits by CMS are acting on the behalf of the federal government and are not required to sign the Sponsor's confidentiality statement prior to the start of an on-site audit (Pursuant to 42 C.F.R. § 423.322(b), employees and contractors of DHHS, such as the MEDICs, may use the information disclosed or obtained in accordance with the regulation only for the purposes of, and to the extent necessary in, carrying out the regulation including, but not limited to, determination of payments and payment-related oversight and program integrity activities).

Sponsors, first tier entities, downstream entities, and related entities are required to cooperate with CMS and CMS' contractors, such as the MEDICs. This cooperation includes providing CMS and/or the MEDICs with access to all requested facilities and records associated in any manner with the Part D program for 10 years (6 years for RDS Sponsors) from the end of the final contract period or completion of an audit, whichever is later. In cases when there is a termination, dispute, or allegation of fraud or similar fault by the Part D plan Sponsor, the record retention requirements may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault (42 C.F.R. § 423.505(e)(4)(ii)).

In addition, random desk audits are necessary for CMS and its designees to cover all oversight within the 3-year audit cycle (See "Part D Oversight Strategy for Contractors/Industry" for additional information). Each random yearly audit should also include at least one area to be audited that overlaps with an area audited in a previous year within the 3-year audit cycle. Randomizing the oversight areas to be audited will

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prevent complacency in any oversight areas audited and ensure readiness for an audit of any oversight area.

CMS has the discretionary authority to perform audits under 42 C.F.R. § 423.505(e)(2) which specifies the right to audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of Sponsors, related entity(s), contractor(s), subcontractor(s), or their transferees that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract or as the Secretary may deem necessary to enforce the contract. When CMS or its designee, e.g. the MEDIC, requests information that will be used for an audit, CMS or its designee will notify the Sponsor of an appropriate time period with which to provide the requested information. This notification will be routed through the Sponsor's account manager. CMS central office and regional office account managers will manage each Sponsor's Part D program operations. Account managers will work with Sponsors to resolve day-to-day compliance issues.

50.2.7 Prompt Responses

...to Detected Offenses and Corrective Action Plans

Developing Prompt Responses to Detected Offenses and Corrective Action Plans

This section discusses recommendations for implementing the regulation requiring that the Part D Sponsor have procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a Part D Sponsor. (42 C.F.R. § 423.504(b)(4)(vi)(G)).

50.2.7.1 Conducting an Inquiry

...a Timely and Reasonable Inquiry of Detected Offenses

Part D Sponsors must conduct a timely, reasonable inquiry into any conduct where evidence suggests there has been misconduct related to payment or delivery of prescription drug items or services under the Part D contract (42 C.F.R. § 423.504(b)(4)(vi)(G)(1)). Such misconduct may occur at the level of the Sponsor or its first tier entities, downstream entities, or related entities. However, regardless of where the misconduct is identified, Sponsors are responsible for initiating a timely and reasonable inquiry.

Potential instances of fraud, waste and abuse may come to the attention of the Part D Compliance Officer or other members of senior management through a number of sources (e.g., employee or beneficiary complaints, audits). Sponsors should initiate a reasonable inquiry immediately, but no later than two weeks from the date the potential misconduct is identified.

A reasonable inquiry includes a preliminary investigation of the matter by the Part D Compliance Officer and/or Special Investigative Unit (SIU) for the Sponsor (see section 50.2.7.2 for information SIUs). In the event the Sponsor does not have either the time or the resources to investigate the potential misconduct it should refer the matter to the MEDIC within two weeks of the date the potential misconduct is identified so the potentially fraudulent or abusive activity does not continue.

As stated previously, it is recognized that Sponsors are not law enforcement entities, and it is not expected that Sponsors pursue fraudulent activities in the same manner that law enforcement would. However, just as other contractors who administer Medicare benefits are responsible for monitoring for wasteful, abusive, and fraudulent

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activities in their organizations, the same expectations hold true for Part D plan sponsors. Once identified, Sponsors should refer the activities to CMS or the appropriate MEDIC. MCS and its contractors will investigate all cases referred as potentially fraudulent and refer them to the appropriate law enforcement agency as warranted (70 Fed. Reg. 4194, 4339 (January 28, 2005)).

50.2.7.2- Special Investigation Units (SIUs)

For those Sponsors who have established SIUs, the following section summarizes CMS' expectations of the roles and responsibilities of SIUs in assisting with Part D fraud, waste and abuse investigations. CMS views the work of the SIUs as crucial to identifying potential fraud, waste and abuse committed by subcontractors involved in the delivery of the prescription drug benefit. A SIU is an internal investigative unit, often separate from the Compliance Office and often staffed by former law enforcement personnel responsible for conducting surveillance, interviews, and other methods of investigation. Some Plans may have units that serve the same function, but do not call them SIU. This section refers to those units as well. Goals of SIUs typically include but are not limited to:

- Reducing or eliminating prescription drug costs due to fraud, waste and abuse.
- Ensuring proper value of prescription drugs, including correct pricing, quantity, and quality.
- Utilizing real-time systems that ensure accurate eligibility, benefits, refills, and pricing at the point of sale and that identify potential adverse drug interactions.
- Reducing or eliminating fraudulent or abusive claims paid for with federal dollars.
- Preventing illegal activities.
- Identifying members with drug addiction problems.
- Identifying and recommending providers for exclusion, including physicians, pharmacists, and PBMs who have defrauded or abused the system.
- Referring potential cases of illegal drug activity, including drug diversion, to the MEDIC and/or law enforcement and conducting case development and support activities for MEDIC and/or law enforcement investigations.
- Assisting law enforcement by providing information needed to develop successful prosecutions.

SIUs are typically accessible via phone, email, Internet message submission, and mail. Suspicions of fraud, waste or abuse typically can be reported to SIUs anonymously. Traditionally, SIUs objectives have been aimed at the conduct of third parties submitting claims to the Sponsor. However, CMS does not interpret the requirement to have in place a program to control fraud, waste and abuse to be limited to the conduct of third parties submitting claims to the Sponsor (42 U.S.C. § 1395w-104). CMS believes in order to have an effective program to control fraud, waste and abuse, Sponsors should have policies and procedures in place to identify and address fraud, waste and abuse at both the Sponsor and the third party levels in the delivery of prescription drugs through the Medicare benefit.

Furthermore, not all Sponsors have SIUs in place, nor does this chapter intend to imply that Sponsors that do not have SIUs should develop them. Instead, since the regulations placed the requirement for Sponsors to have a comprehensive fraud and abuse program within the compliance plan requirements, this chapter provides guidance to Sponsors on how to incorporate a comprehensive fraud, waste and abuse program

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within their compliance programs. To the extent that a Sponsor has an existing fraud, waste and abuse program that is operated through its SIU, the Sponsor should make certain that the SIU and compliance department work closely together to ensure that the Medicare Prescription Drug benefit is reasonably protected from fraudulent, abusive and wasteful schemes throughout the administration and delivery of prescription drugs, both at the Sponsor level and at the first tier entity, downstream entity, and related entity levels.

50.2.8 - Corrective Actions

Part D Sponsors must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to potential violations (42 C.F.R. § 423.504(b)(4)(vi)(G)(2)).

50.2.8.1 - Conducting Appropriate Corrective Actions

Corrective actions should be designed to correct the underlying problem that results in program violations and prevent future misconduct. A corrective action plan should be tailored to address the particular misconduct identified. The corrective action plan should provide structure with timeframes so as not to allow continued misconduct. When developing corrective actions for misconduct committed by a Sponsor's first tier entity, downstream entity, or related entity the elements of the corrective action should be detailed in a written agreement with the entity that includes ramifications should the subcontractor fail to satisfactorily implement the corrective action. Likewise, the elements of the corrective action plan that addresses misconduct committed by the Sponsor should be documented, and should include ramifications should the Sponsor or its employee(s) fail to satisfactorily implement the corrective actions. Corrective action plans should continue to be monitored after the implementation to ensure that they are effective.

50.2.8.2 - Recommended Procedures

...for Reporting by Sponsors

The reporting of potential fraud to CMS and/or its designee is an important mechanism for protecting Medicare beneficiaries from harm and the Medicare Trust Fund from fraud, waste and abuse. While the regulations make it clear that self-reporting of potential fraud is voluntary (42 C.F.R. § 423.504(b)(4)(vi)(H)) CMS believes that self-reporting of fraud, waste and abuse is a critical element to an effective program to control fraud, waste and abuse. CMS believes that Sponsors should self-report potential fraud discovered at the plan level, and also report potential fraud that is discovered at the first tier entity, downstream entity, or related entity levels. This is especially encouraged when potential fraud is discovered at the first tier entity, downstream entity, or related entity level because the conduct discovered may very well be systemic and the MEDIC will have information across Sponsors to compare.

Sponsors should notify the MEDICs of potential fraud, waste or abuse in accordance with the guidelines described below. The MEDICs will refer potential fraud or misconduct to law enforcement when appropriate. Issues that are referred to the MEDIC and are determined not to be potential fraud will be returned to the Sponsor to be addressed. Sponsors with SIUs or other appropriate resources are encouraged to investigate potentially fraudulent activity so they can make a determination whether

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potential fraud or misconduct has occurred. Where Sponsors do not have the time, resources, or experience to adequately investigate potentially fraudulent misconduct, CMS recommends the matter be referred to the MEDIC within two weeks from when the potentially fraudulent activity is discovered. In other words, where the Sponsor cannot determine whether or not the conduct has risen to the level of potential fraud due to limited resources, the Sponsor should refer the activity to the MEDIC for investigation.

If after conducting a reasonable inquiry by the Sponsor (e.g. the Part D Compliance Officer, the SIU) it is determined that potential fraud or misconduct related to the Part D program has occurred, the conduct should be referred to the MEDIC promptly, but no later than 60 days after the determination that a violation may have occurred. To the extent that potential fraud is discovered at the first tier entity, downstream entity, or related entity levels, the Sponsor should refer the conduct to the MEDIC sooner so that the MEDIC can help identify and address any scams or schemes. If this timeframe cannot be met, Sponsors should contact the MEDIC for further guidance.

Sponsors are also encouraged to consider reporting the conduct to government authorities such as the Office of Inspector General (through the OIG's Provider Self-Disclosure Protocol), or the Department of Justice. All health care providers doing business with Medicare that want to disclose violations of law are eligible to disclose fraudulent conduct under the Provider Self-Disclosure Protocol (63 Fed. Reg. 58,399 (1998)); There are no pre-disclosure requirements or preliminary qualifying characteristics that must be met. The Protocol offers a detailed step-by-step explanation of how a provider should proceed in reporting and assessing the extent of wrong doing and how the OIG will go about verifying irregularities. Self-reporting offers Sponsors the opportunity to minimize the potential cost and disruption of a full scale audit and investigation, to negotiate a fair monetary settlement, and to potentially avoid an OIG permissive exclusion preventing the entity from doing business with the Federal health care programs.

50.2.8.3 - Referrals to the MEDICs

Once it is determined that a referral should be made to the MEDIC, Sponsors should develop a referral package that includes, to the extent available, the following:

- Provider name, all known billing and tax identification numbers, and addresses.
- Type of provider involved in the allegation and the perpetrator, if an employee of the provider.
- Type of item or service involved in the allegation.
- Place of service.
- Nature of the allegation(s).
- Timeframe of the allegation(s).
- Narration of the steps taken and information uncovered during the Sponsor's screening process.
- Date of Part D service, drug code(s).
- Beneficiary name, beneficiary Health Insurance Claim (HIC) number, address and telephone number.
- Name and telephone number of the Sponsor employee who received the complaint.
- Contact information of the complainant, if not the beneficiary.
- All documents pertaining to prior sanctions and/or compliance history and corrective actions taken, if any.

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Because this is not an all-inclusive list, the MEDIC has the right to request additional information so the matter can be resolved. If the MEDIC requests additional information the Sponsor shall furnish the requested information within 30 days, unless the MEDIC otherwise specifies. In some rare instances, there may be a need to acquire information in less than 30 days, e.g., in case of risk to patient health. In those instances, all parties involved will be notified as soon as possible. Additionally, Sponsors should provide updates to the MEDIC when new information regarding the matter is identified.

MEDICs will further investigate referrals from Sponsors, develop the investigations, and make referrals to appropriate law enforcement agencies or other outside entities when necessary. To the extent it is feasible, the MEDIC will keep the Sponsor apprised of the development and status of the investigation. If a MEDIC determines a referral to be a matter related to non-compliance or mere error rather than fraud or abuse, it will be returned to CMS and/or the Sponsor for appropriate follow-up.

As mentioned in Section 30 of this Chapter, CMS will release future information regarding Sponsors' expectations and responsibilities regarding interactions with the MEDICs when task orders are awarded.

60 Implementing a Comprehensive Program

...To Detect, Correct and Prevent Fraud, Waste and Abuse and Procedures to Voluntarily Self-Report Potential Fraud or Misconduct

Sponsors must have a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority (42 C.F.R. § 423.504(b)(4)(vi)(H)).

As stated in section 50.1, Part D Sponsors may implement a program to control fraud, waste and abuse in one of two ways:

2. A fraud, waste and abuse program that considers the methods described in this chapter and incorporates them into the appropriate components of a Sponsor's existing structure; or
3. Fraud, waste or abuse provisions can be integrated into each of the elements of the Sponsor's existing compliance plan. (This chapter provides guidance on how to add a fraud, waste and abuse element to each component of a general compliance plan.)

In an effort to consolidate the various compliance requirements in the Part D statutes and regulations (70 Fed. Reg. 4194 (2005)), CMS included the requirement to have a program that controls fraud, waste and abuse as a component of a Part D Plan Sponsor's overall compliance plan. Section 50 of this chapter details the seven core elements of a compliance plan as required by regulation, and expands upon the regulatory requirements to provide guidance to Sponsors on how to develop a comprehensive Part D fraud, waste and abuse program by integrating a fraud, waste and abuse program inside of the Sponsor's compliance plan.

Self-reporting of potential fraud was addressed as an available corrective action in section 50.2.8.2. Self-reporting of fraud, waste and abuse is a critical element to an effective program to control fraud, waste and abuse. If after conducting a reasonable inquiry by the Sponsor (e.g. the Part D Compliance Officer, the SIU) it is determined

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that potential fraud or misconduct has occurred, the conduct should be referred to the MEDIC promptly, but no later than 60 days after the determination that a violation may have occurred. To the extent that potential fraud is discovered at the first tier entity, downstream entity, or related entity levels, the Sponsor should refer the conduct to the MEDIC sooner so that the MEDIC can help identify and address any scams or schemes. If this timeframe cannot be met, Sponsors should contact the MEDIC for further guidance.

Sponsors are also encouraged to consider reporting the conduct to other government authorities such as the Office of Inspector General (through the OIG's Provider Self-Disclosure Protocol), or the Department of Justice as discussed in section 50.2.8.2.

70 - Examples of Risks for Fraud, Waste and Abuse

In this section, potential schemes, risks, and vulnerabilities to the Part D benefit are broadly discussed. This section does not detail the complexity of analysis required to adequately determine if fraud, waste or abuse have occurred. However, this section should be helpful for Sponsors in identifying potential risk areas present in the Part D benefit. This section also identifies the various key stakeholders that are instrumental in the delivery of the Part D benefit, and some of the risks associated with those stakeholders. The schemes, risks and vulnerabilities can be perpetrated by multiple stakeholders and their impact may vary by degree of severity. Given that Sponsors maintain ultimate responsibility for delivery of the benefit, Sponsors should review these risks and develop their program to control fraud, waste and abuse accordingly. This list is not an exhaustive discussion of all the potential stakeholders or vulnerabilities that may be present in the Part D benefit. Further, the schemes identified with each stakeholder are not necessarily unique to that stakeholder, and may be a scheme, risk or vulnerability associated with other stakeholders. These examples of fraud, waste and abuse are not intended to modify any substantive requirements or impose new requirements on Sponsors.

70.1 - Examples of Risks

...for Part D Plan Sponsors, PBMs, Pharmacies, Prescribers, Wholesalers, Pharmaceutical Manufacturers, and Medicare Beneficiaries

70.1.1 - Part D Plan Sponsor

...Fraud, Waste and Abuse (PDP, MA-PD, Cost Plans, Employer- or Union-Sponsored Plans)

The following section describes examples of Sponsor fraud, waste and abuse. Because some Sponsors operate their own PBMs or have in-house PBM functions, some of the examples cited in the PBM section are applicable here. Examples of potential fraud, waste and abuse include but are not limited to:

- *Failure to provide medically necessary services:* Fails to provide, to a Part D plan enrollee, medically necessary items or services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to affect) the enrollee.

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- *Marketing Schemes*: When a Sponsor, or its subcontractor, violates the Medicare marketing guidelines, or other federal or state laws, rules, and regulations to improperly enroll beneficiaries in a Part D Plan. Examples of such violations include, but are not limited to:
 - Offering beneficiaries a cash payment as an inducement to enroll in Part D;
 - Unsolicited door-to-door marketing;
 - Use of unlicensed agents;
 - Enrollment of beneficiary without their knowledge or consent;
 - Stating that a marketing agent/broker works for or is contracted with the Social Security Administration or CMS;
 - Misrepresents the product being marketed as an approved Part D Plan when it actually is a Medigap policy or non-Medicare drug plan;
 - Misrepresents the Medicare Advantage or Prescription Drug Plan being marketed (i.e., enrolling Medicare beneficiaries in a MA-PD when they wanted a PDP);
 - Requests financial beneficiary information or check numbers (i.e., potential identity theft by a Part D Plan's marketing agents).
 - Requires beneficiaries to pay up front premiums.
- *Improper bid submissions*: The Sponsor inappropriately overestimates or underestimates the bid to manipulate risk corridors and/or payments, including miscalculations of administrative ratio costs within the bids (wrong service lines).
- *Payments for excluded drugs*: Sponsors must ensure that they only provide coverage for “covered Part D drugs,” as listed in their approved formularies, and in accordance with section 1860D-2(e)(2) (42 C.F.R. § 423.100).
- *Multiple billing*: Several payers billed for the same prescription, except as required for coordination of benefit transactions, such as the same prescription being covered and paid for under Medicare Part A or Part B, and then a second time under Part D, and/or possibly Medicaid.
- *Non-Compendium Payments*: Payments for Part D drugs that are not for a “medically accepted indication” (See 42 U.S.C. § 1395w-102).
- *Inappropriate formulary decisions*: Where Sponsors or PBMs engage in formulary decision processes in which costs take priority over criteria such as clinical efficacy and appropriateness.
- *Inappropriate Enrollment/Disenrollment*: Improperly reporting enrollment and disenrollment data to CMS to inflate prospective payments. For example, Sponsor fails to effect timely disenrollment of beneficiary from CMS systems upon beneficiary's request.
- *Appeals process handled incorrectly*: Medicare beneficiary denied their right to appeal or denied a timely appeal.
- *Adverse selection*: Selecting or denying beneficiaries based on their illness profile or other discriminating factors. The Sponsor may anticipate costs being too high with certain beneficiaries with many or severe comorbid diseases, and improperly acts to expel or refuses to enroll a beneficiary in violation of the regulations or the contract.
- *False information*: Plan misrepresents or falsifies information it furnishes to CMS or to an individual under the Part D drug benefit program.
- *Delinquent reimbursements*: Beneficiary is not reimbursed by the plan following retroactive low income subsidy determination.
- *Duplicative premiums*: Receiving duplicative co-pays or premiums from beneficiaries.

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- *Excessive premiums*: Imposes on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under the regulation.
- *Inaccuracies in eligibility or coordination of benefits*: Inaccurate or incomplete information on eligibility or benefits can lead to wasteful expenditure on drugs. Part D Plan Sponsors and/or PBMs can mitigate waste associated with inaccurate information through the use of real-time systems to verify eligibility, available benefits and payer status.
- *Incorrect calculation of TrOOP*: Miscalculation of a beneficiary's TrOOP to manipulate beneficiary status in coverage (e.g., falsifying TrOOP calculations to keep beneficiaries in the coverage gap, or falsifying TrOOP calculations to push beneficiaries through the coverage gap into catastrophic coverage), or other incorrect calculation of TrOOP that may result in improper payments by CMS or beneficiaries.
- *Inaccurate data submission*: Sponsor submits inaccurate or incomplete prescription drug event (PDE) data or Part D plan quarterly data.
- *Catastrophic coverage manipulation*: Sponsors manipulate catastrophic coverage to increase payment by CMS.
- *Failure to disclose or misrepresentation of rebates, discounts or price concessions*: Sponsor fails to disclose or misrepresents rebates, discounts, price concessions, or other value added gifts, including concessions offered by pharmaceutical manufacturers.
- *Bait and switch pricing*: When a beneficiary is led to believe that a drug will cost one price, but at the point of sale the beneficiary is charged a higher amount. This includes frequent formulary changes to induce beneficiaries to sign up for specific drugs that are later removed.
- *Manipulation of low-income subsidy enrollees*: Sponsor provides false or misleading information regarding the number of its members who have applied for and qualify for the low income subsidy in order to receive unwarranted low income subsidy payments.

70.1.2 - PBM Fraud, Waste and Abuse

The following section describes examples of Pharmacy Benefit Managers (PBM) fraud, waste and abuse. Because many Sponsors operate their own PBMs or perform the PBM function themselves, some of the examples cited in the Part D Plan section are applicable here. Examples of potential fraud, waste and abuse include but are not limited to:

- *Prescription drug switching*: The PBM receives a payment to switch a beneficiary from one drug to another or influence the prescriber to switch the patient to a different drug.
- *Unlawful remuneration*: PBM receives unlawful remuneration in order to steer a beneficiary toward a certain plan or drug, or for formulary placement. Includes unlawful remuneration from vendors beyond switching fees.
- *Inappropriate formulary decisions*: PBMs or their P&T committees make formulary decisions where cost takes precedence over clinical efficacy and appropriateness of formulary drugs.
- *Prescription drug splitting or shorting*: PBM mail order pharmacy intentionally provides less than the prescribed quantity and does not inform the patient or make arrangements to provide the balance but bills for the fully-prescribed amount. Splits prescription to receive additional dispensing fees.

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- *Failure to offer negotiated prices:* Occurs when a PBM does not offer a beneficiary the negotiated price of a Part D drug.

70.1.3 - Pharmacy Fraud, Waste and Abuse

The following section describes examples of pharmacy fraud, waste and abuse.

Examples of potential fraud, waste and abuse include but are not limited to:

- *Inappropriate billing practices:* Inappropriate billing practices at the pharmacy level occur when pharmacies engage in the following types of billing practices:
 - Incorrectly billing for secondary payers to receive increased reimbursement.
 - Billing for non-existent prescriptions.
 - Billing multiple payers for the same prescriptions, except as required for coordination of benefit transactions.
 - Billing for brand when generics are dispensed.
 - Billing for non-covered prescriptions as covered items.
 - Billing for prescriptions that are never picked up (i.e., not reversing claims that are processed when prescriptions are filled but never picked up).
 - Billing based on “gang visits,” e.g., a pharmacist visits a nursing home and bills for numerous pharmaceutical prescriptions without furnishing any specific service to individual patients.
 - Inappropriate use of dispense as written (“DAW”) codes.
 - Prescription splitting to receive additional dispensing fees.
 - Drug diversion.
- *Prescription drug shorting:* Pharmacist provides less than the prescribed quantity and intentionally does not inform the patient or make arrangements to provide the balance but bills for the fully-prescribed amount.
- *Bait and switch pricing:* Bait and switch pricing occurs when a beneficiary is led to believe that a drug will cost one price, but at the point of sale the beneficiary is charged a higher amount.
- *Prescription forging or altering:* Where existing prescriptions are altered, by an individual without the prescriber’s permission to increase quantity or number of refills.
- *Dispensing expired or adulterated prescription drugs:* Pharmacies dispense drugs that are expired, or have not been stored or handled in accordance with manufacturer and FDA requirements.
- *Prescription refill errors:* A pharmacist provides the incorrect number of refills prescribed by the provider.
- *Illegal remuneration schemes:* Pharmacy is offered, or paid, or solicits, or receives unlawful remuneration to induce or reward the pharmacy to switch patients to different drugs, influence prescribers to prescribe different drugs, or steer patients to plans.
- *TrOOP manipulation:* When a pharmacy manipulates TrOOP to either push a beneficiary through the coverage gap, so the beneficiary can reach catastrophic coverage before they are eligible, or manipulates TrOOP to keep a beneficiary in the coverage gap so that catastrophic coverage is never realized.
- *Failure to offer negotiated prices:* Occurs when a pharmacy does not offer a beneficiary the negotiated price of a Part D drug.

70.1.4 - Prescriber Fraud, Waste and Abuse

The following section describes examples of prescriber fraud, waste and abuse.

Examples of potential fraud, waste and abuse include but are not limited to:

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- *Illegal remuneration schemes:* Prescriber is offered, or paid, or solicits, or receives unlawful remuneration to induce or reward the prescriber to write prescriptions for drugs or products.
- *Prescription drug switching:* Drug switching involves offers of cash payments or other benefits to a prescriber to induce the prescriber to prescribe certain medications rather than others.
- *Script mills:* Provider writes prescriptions for drugs that are not medically necessary, often in mass quantities, and often for patients that are not theirs. These scripts are usually written, but not always, for controlled drugs for sale on the black market, and might include improper payments to the provider.
- *Provision of false information:* Prescriber falsifies information (not consistent with medical record) submitted through a prior authorization or other formulary oversight mechanism in order to justify coverage. Prescriber misrepresents the dates, descriptions of prescriptions or other services furnished, or the identity of the individual who furnished the services.
- *Theft of prescriber's DEA number or prescription pad:* Prescription pads and/or DEA numbers can be stolen from prescribers. This information could illegally be used to write prescriptions for controlled substances or other medications often sold on the black market. In the context of e-prescribing, includes the theft of the provider's authentication (log in) information.

70.1.5 - Wholesaler Fraud, Waste and Abuse

The following section describes examples of wholesaler fraud, waste and abuse.

Examples of potential fraud, waste and abuse include but are not limited to:

- *Counterfeit and adulterated drugs through black and grey market purchases:* This includes but is not limited to fake, diluted, expired, and illegally imported drugs.
- *Diverters:* Brokers who illegally gain control of discounted medicines intended for places such as nursing homes, hospices and AIDS clinics. Diverters take the discounted drugs, mark up the prices, and rapidly move them to small wholesalers. In some case the pharmaceuticals may be marked up six times before being sold to the consumer.
- *Inappropriate documentation of pricing information:* Submitting false or inaccurate pricing or rebate information to or that may be used by any Federal health care program.

70.1.6 -- Pharmaceutical Manufacturer Fraud, Waste and Abuse

The following section describes examples of potential or suspect Pharmaceutical Manufacturer fraud, waste and abuse. These areas, and others are discussed in the "OIG's Compliance Program Guidance for Pharmaceutical Manufacturers, Notice" 68 Fed. Reg. 23733-23739 (2003). Please refer to this guidance for further risk details and compliance implementation and development. Examples of potential fraud, waste and abuse include but are not limited to:

- *Lack of integrity of data to establish payment and/or determine reimbursement:* Pharmaceutical manufacturers may be liable under the False Claims Act, civil monetary penalties and/or the Federal Anti-Kickback statute if government reimbursement for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, including rebates, directly or indirectly, and the manufacturer has knowingly failed to generate or report such information completely and accurately.

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- *Inappropriate documentation of pricing information:* Manufacturers must maintain accurate and complete documentation of their pricing information.
- *Kickbacks, inducements, and other illegal remuneration:* The Anti-Kickback statute may be implicated by the following types of activities:
 - Inappropriate marketing and/or promotion of products (sales, marketing, discounting, etc.) reimbursable by federal health care programs.
 - Inducements offered if the purchased products are reimbursable by any of the federal health care programs. Examples of potentially improper inducements, including inappropriate discounts, inappropriate product support services, inappropriate educational grants, inappropriate research funding, or other inappropriate remuneration.
- *Formulary and formulary support activities:* Examples of potential fraud and abuse include inappropriate relationships with formulary committee members, payments to PBMs, and formulary placement payments in order to have manufacturer's products included on a Plan's formulary.
- ***Inappropriate relationships with physicians: Potentially inappropriate relationships between pharmaceutical manufacturers and physicians include:***
 - "Switching" arrangements, when manufacturers offer physicians cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product.
 - Incentives offered to physicians to prescribe medically unnecessary drugs.
 - Consulting and advisory payments, payments for detailing, business courtesies and other gratuities, and educational and research funding.
 - Improper entertainment or incentives offered by sales agents.
- *Illegal off-label promotion:* Illegal promotion of off-label drug usage through marketing, financial incentives, or other promotion campaigns.
- *Illegal usage of free samples:* Providing free samples to physicians knowing and expecting those physicians to bill the federal health care programs for the samples.

70.1.7 - Medicare Beneficiary Fraud, Waste and Abuse Risks

Typically, Medicare beneficiaries tend to be victims, not perpetrators, of fraudulent, wasteful or abusive schemes. However, there are some schemes committed by beneficiaries that may impact payers. The following section describes examples of the types of fraud, waste or abuse that could be perpetrated by beneficiaries in Part D, as well as examples where beneficiaries might be victimized. Examples of potential fraud, waste and abuse include but are not limited to:

- *Misrepresentation of status:* A Medicare beneficiary misrepresents personal information, such as identity, eligibility, or medical condition in order to illegally receive the drug benefit. Enrollees who are no longer covered under a drug benefit plan may still attempt to use their identity card to obtain prescriptions.
- *Identity theft:* Perpetrator uses another person's Medicare card to obtain prescriptions.
- *TrOOP manipulation:* A beneficiary manipulates TrOOP to push through the coverage gap, so the beneficiary can reach catastrophic coverage before they are eligible.
- *Prescription forging or altering:* Where prescriptions are altered, by someone other than the prescriber or pharmacist with prescriber approval, to increase quantity or number of refills.
- *Prescription diversion and inappropriate use:* Beneficiaries obtain prescription drugs from a provider, possibly for a condition from which they do not suffer, and gives or

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sells this medication to someone else. Also can include the inappropriate consumption or distribution of a beneficiary's medications by a caregiver or anyone else.

- *Resale of drugs on black market*: Beneficiary falsely reports loss or theft of drugs or feign illness to obtain drugs for resale on the black market.
- *Prescription stockpiling*: Beneficiary attempts to "game" their drug coverage by obtaining and storing large quantities of drugs to avoid out-of-pocket costs, to protect against periods of non-coverage (i.e., by purchasing a large amount of prescription drugs and then disenrolling), or for purposes of resale on the black market.
- *Doctor shopping*: Beneficiary or other individual consults a number of doctors for the purpose of inappropriately obtaining multiple prescriptions for narcotic painkillers or other drugs. Doctor shopping might be indicative of an underlying scheme, such as stockpiling or resale on the black market.
- *Improper Coordination of Benefits*: Improper coordination of benefits where beneficiary fails to disclose multiple coverage policies, or leverages various coverage policies to "game" the system.
- *Marketing Schemes*: A beneficiary may be victimized by a marketing scheme where a Sponsor, or its agents or brokers, violates the Medicare Marketing Guidelines, or other applicable Federal or state laws, rules, and regulations to improperly enroll the beneficiary in a Part D Plan.

70.2 - Additional Vulnerabilities

In addition to the above mentioned potential schemes, risks, and vulnerabilities, listed below are four other major areas of concern.

70.2.1 - Coordination with State Pharmacy Assistance Programs

42 C.F.R. § 423.464 requires coordination of benefits with other providers of prescription drug coverage, including State Pharmacy Assistance Programs (SPAPs). SPAPs under Part D will be providing wrap-around benefits in the form of financial assistance by supplementing Part D premiums prior to and for the "coverage gap" portion of the benefit. Oversight of this coordination is essential to:

- Prevent double billing.
- Ensure that the Part D Plans remain the primary payer.
- Ensure that benefits are coordinated so that TrOOP tracking of SPAPs is taken into account.

Additionally, an oversight and monitoring program will also ensure that expenditures by other plans are excluded for the purposes of reaching the beneficiaries true out-of-pocket (TrOOP) expenditures in the TrOOP calculation.

70.2.2 - NABP and NADDI

...Lists of Susceptible Pharmaceuticals

In February 2004, the National Association of Boards of Pharmacy (NABP) released the updated Model Rules for the Licensure of Wholesale Distributors. The formulation of the updated Model Rules was a collaborative effort among NABP, pharmacy representatives, the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), state regulatory authorities, and the wholesale distributor industry to protect the public from the use of counterfeit drugs and devices. The drugs most vulnerable to counterfeiting are usually single source injectable drugs, are commonly

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prescribed, have substantial wholesale cost with revenue-generating power, or are in limited supply.

Additionally, the National Association of Drug Diversion Investigators, Inc., (NADDI),⁹⁰ publishes a list of abused pharmaceutical substances. These are narcotics that are most frequently abused or illegally sold/counterfeited.

70.2.3 -Drugs Excluded From Part D Coverage

Pursuant to section 1927 of the Social Security Act and the final Part D regulations at 42 C.F.R. § 423.100, a Part D drug is:

- Defined as a drug that may be dispensed only upon a prescription;
- Approved by FDA for safety and efficacy;
- A biological product;
- Insulin and medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze; or
- A vaccine.

A drug is considered to be a Part D drug only if prescribed for a “medically accepted indication.” Drugs may not be covered under Part D if they are not prescribed for a medically accepted indication. Coverage for other than a medically accepted indication is not permitted under the statute because such drugs would not be considered Part D drugs. In accordance with section 1860D-2(e)(2) of the Act, covered Part D drugs shall specifically exclude drugs or classes of drugs, or their medical uses, which may be excluded or restricted from coverage under the Medicaid program (42 U.S.C. § 1396r-8), with the exception of smoking cessation agents. Thus, it is the responsibility of the Part D plans to prohibit the inappropriate payment for these excluded drugs or indications, i.e. edits or prior authorization.

70.2.4 - Part B and Part D Coverage Issues

Prior to the implementation of the Medicare Modernization Act (MMA), Medicare beneficiaries received coverage for a limited number of drugs provided under Parts A and B. With the implementation of the prescription drug benefit, there is potential for inappropriate duplicate coverage between A, B, and D drugs. While the potential crossover between Parts A and D is unlikely, Medicare Parts B and D contain specific drugs covered under both programs. As a consequence, there is a greater likelihood of crossover between Part B and D drugs; and it will be incumbent on Sponsors to have mechanisms in place to ensure drugs are adjudicated correctly to either Part B or D. The statutory definition of “covered Part D drug” states that Sponsors must exclude any drug that would otherwise be considered a Part D drug for which, as so prescribed and dispensed or administered to that individual, payment would be available under Parts A or B (42 U.S.C. § 1395w-102; 42 C.F.R. § 423.100).

The implementation of the Part D benefit does not alter coverage or associated rules for drugs currently covered under Part B. Part B covers drugs in a variety of settings. In almost all of these settings the question of whether coverage should be provided under Part D will not arise because the drugs are being provided in the context of a service or procedure and thus the drugs are covered under Part B. For a limited number of categories, however, pharmacists and infusion providers will have to determine whether to bill Part B or Part D; and Sponsors will need to confirm whether Part D is being billed

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correctly. The following are some of the potential schemes that could be perpetrated due to the crossover between Parts B and D;

- **Home Infusion** - Home infusion pharmacies are often paid delivery and dispensing fees for certain self-injectable medications (e.g., Epogen, Procrit) even if the beneficiary self-administers. As home infusion pharmacies will be part of both Part B and Part D networks, these pharmacies might inappropriately submit the claim for coverage under inappropriate benefit.
- **Duplicate Billing** - Claims could be submitted by a provider under both medical for Part B and pharmacy for Part D. Control mechanisms may include prior authorization processes that identify by diagnosis and other qualifying factors if a drug is covered under Part B or Part D and prevents the claim from being paid by the non-covered component. Additional control mechanisms and retrospective review for duplicate claims may vary between MA-PD and PDP due to different levels of access to medical history and claims.
- **Crossover Drugs** - Some of the medications that will be crossover drugs are traditionally purchased and administered by the physician's office or clinic. These medications represent a potential revenue stream to the physician's office. If a PDP or MA-PD carves out purchase of the medications for Part D coverage to a specialty or mail service pharmacy that will deliver patient-specific medication to a physician's office, this could represent a loss of revenue. In some cases, the patient may be able to purchase the pharmaceutical under the Part D benefit at a community pharmacy and bring it to the physician's office for administration. In these circumstances, the physicians may inappropriately bill for both the drug and the injection of the drug under Part B.
- **Differential Copays** - Beneficiary may have different cost sharing obligations if a crossover drug is paid under Part B versus Part D, or vice versa. A beneficiary could 'game the system' to lower their cost sharing obligations by improperly submitting a claim to the inappropriate payer.

It is incumbent upon the Sponsor to institute a control, such as a prior authorization to ensure that the pharmacy is billing the correct program. Sponsors should have procedures in place to reverse claims in case a pharmacy is paid in error under Part D for what should have been a Part B covered product.

For additional detail related to coverage rules and/or Part B versus Part D crossover, please refer to <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/>.

80 - Other Part D Sponsor Federal Compliance Considerations

The effective implementation of the Part D Drug Benefit relies on Sponsors' compliance with all applicable federal and state regulatory requirements related to the Medicare program. Sponsors, first tier entities, downstream entities, and related entities must also ensure that legal/ethical standards are met. Sponsors will need to continually monitor and update their compliance program to incorporate any modifications to applicable regulations and contractual requirements.

CMS strongly encourages Sponsors to alert MEDICs/CMS of any potential fraud or misconduct relating to the Part D program and the delivery of prescription drugs. Sponsors that self-report violations may receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines. When MEDICs

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discover Sponsor violations of criminal, civil or administrative law, they will report them to the appropriate law enforcement entity. Both the DOJ and the OIG have longstanding policies favoring self-disclosure.

The following section outlines some of the key federal compliance considerations (in addition to the MMA) that Sponsors may need to comply with as they fulfill their program integrity functions.

80.1 - The False Claims Act

Sponsors should devise their compliance programs so that their policies and procedures are consistent with the Federal Civil False Claims Act (31 U.S.C. §§ 3729-3733). The False Claims Act prohibits knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the federal government or its agents, like a carrier, other claims processor, or state Medicaid program (31 U.S.C. § 3729(a)(1)-(7)).

When submitting claims data to CMS for payment, Sponsors and their subcontractors must certify that the claims data is true and accurate to the best of their knowledge and belief. (42 C.F.R. § 423.505(k)(3)). The False Claims Act is enforced against any individual/entity that knowingly submits (or causes another individual/entity to submit) a false claim for payment to the Federal government. In addition, parties have a continuing obligation to disclose to the government any new information indicating the falsity of the original statement. Since Sponsors maintain ultimate responsibility for adhering to all terms and conditions of its contract with CMS, they must monitor their subcontractors for compliance with all applicable regulations. (42 C.F.R. § 423.504(i)).

80.2 - The Anti-Kickback Statute

Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward business payable (or reimbursable) under the Medicare or other Federal health care programs. In addition to applicable criminal sanctions, an individual or entity may be excluded from participation in the Medicare and other Federal health care programs and subject to civil monetary penalties (42 U.S.C. § 1320a-7b (a)(i)).

For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. Sponsors shall have policies and procedures employed to ensure that illegal remuneration is not permitted and shall specify follow-up procedures if they uncover unlawful remuneration schemes (42 C.F.R. § 423.504(b)(4)(vi)(A) & (G)).

80.3 – HIPAA

...The Health Insurance Portability and Accountability Act

Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (codified as amended in scattered sections of 18 U.S.C. and 42 U.S.C.).

Among other things, the Health Insurance Portability and Accountability Act (HIPAA), was enacted for the purpose of improving the efficiency and effectiveness of health

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information systems through the establishment of standards and requirements for the electronic transmission of certain health information. This purpose has been effectuated through the promulgation of various regulations including those establishing standards for certain electronic transactions, minimum security requirements, and minimum privacy protections for individually identifiable health information that is held by covered entities (i.e., protected health information). Additional rules have or will establish national identifiers under HIPAA for providers, plans and employers. Covered entities include health plans, health care clearing houses and certain health care providers (namely those that conduct covered transactions).

The Office for Civil Rights (OCR) is the Departmental component responsible for implementing and enforcing the privacy regulations. The Centers for Medicare and Medicaid Services (CMS) is the Departmental component responsible for implementing and enforcing the other HIPAA regulations.

Implementing these standards will improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange in health care.

80.4 - The Freedom of Information Act (FOIA)

The Freedom of Information Act (FOIA) is codified at 5 U.S.C. §552. Its basic purpose is to promote the continued existence of an informed citizenry. More generally, FOIA makes information collected by government agencies available to the public. Consistent with the approach under the Part C program, CMS will not release information under the Part D program that would be considered proprietary in nature or that would tend to stifle the availability of discounts or rebates from pharmaceutical manufacturers negotiated by Part D plans or their first tier entities, downstream entities, or related entities. Most FOIA provisions affect how and when CMS is required (or restricted) from releasing information submitted by Sponsors and should not affect how or when Sponsors release information to CMS.

PART IV

Congressional Testimony

This part of the text looks at Congressional Testimony, some of it “on the road.” The information is from the 1990’s, the dollar amounts are huge. What goes around comes around. Some of the scams and solutions may seem familiar from the first part of this book. Not to worry; a new Marshall is perpetually on the horizon, coming to clean up Dodge.

Keep in mind that the Health Care Finance Administration (HCFA) was the parent organization for Medicare and Medicaid before the current reorganization. See if you can make the connection between HCFA policy and the procedure as reported to, and by, the Congressional Committee. Interspersed in the testimony are **[bracketed subheadings, boldface]**. These are editorial inserts, a part of this text, not the original record. They are placed there to aid in understanding, categorizing and summarizing the testimony.

A Hearing in North Texas

Previous was a US Senate hearing. This is how a subcommittee hearing of the US House of Representatives views the same issue.

MEDICARE WASTE, FRAUD AND ABUSE: A REGIONAL PERSPECTIVE

MONDAY, MARCH 2, 1998

[In the hearing that follows, not a single participant pays homage to Texas Independence Day]

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Colleyville, TX

The subcommittee met, pursuant to notice, at 3:30 p.m., in The Assembly Hall, Colleyville Community Center, 5300 Bluebonnet Drive, Colleyville, Texas, Hon. Joe Barton (chairman) presiding.

Members present: Representatives Barton, Ganske, and Coburn.

Staff Present: Matthew D. Saylor, majority counsel.

Mr. BARTON. The Subcommittee on Oversight and Investigations for the Commerce Committee for the U.S. House of Representatives will come to order. I am

Congressman Joe Barton, I am the chairman. With me, I have Congressman Greg Ganske of Iowa and Congressman Tom Coburn of Oklahoma.

Congressman Ron Klink, the ranking minority member from Pittsburgh, was scheduled to attend, but could not attend because of a death in the family. I have been asked to enter into the record his statement, dated February 27, 1998, to the Honorable Joe Barton, Chairman, Subcommittee on Oversight and Investigations.

"Dear Mr. Chairman, regrettably due to the recent passing of my father-in-law, I will not be able to attend the Oversight and Investigations Field Hearing in Texas on March 2. I want to commend your interest in waste, fraud, and abuse, and encourage that as you have stated, 'It will only be the beginning of a series of health care hearings you intend to hold on that issue.' In particular, I appreciate your willingness to look to other venues such as Pittsburgh for additional field hearings.

"Lastly, I would appreciate it if you would have this letter entered into the record so that the record is clear as to why I am not able to attend. I look forward to working with you on these and other important issues. Sincerely, Congressman Ron Klink, Member of Congress, State of Pennsylvania." So that letter is entered into the record. I want to thank the city of Colleyville for hosting us in this beautiful new community center. It's been opened approximately 1 month, I am told.

Today, we are going to continue a series of hearings related to Medicare waste, fraud, and abuse. We have been reviewing this issue in Washington and will continue to do so, but I wanted to come to Texas today to gain a regional perspective on the problem and to hear from those who fight it daily as well those who see firsthand what is happening in their particular industry.

As chairman of the Oversight and Investigations Subcommittee, I am committed to assuring that Medicare tax dollars, your money, will be used to pay for health care costs of our elderly and not used to fund Medicare schemes of the month. The theft; or misuse of billions in Medicare dollars every year deprives elderly beneficiaries of the health care that they so dearly depend on.

Medicare provides Federal health insurance for approximately 38 million Americans. By the year 2000, it is expected that Medicare will process over 1 billion claims annually and pay out more than \$242 billion in benefits. As the government's largest health program, Medicare accounts for 13 percent of all Federal spending. And it unfortunately continues to be an attractive target for unscrupulous providers.

In a report released last July, the Inspector General of the Department of Health and Human Services, estimated that in fiscal year 1996, improper payments totaled over \$23 billion I understand that the Inspector General did not quantify what amount was attributable to fraud, simply instead stating that improper payments ranged from inadvertent mistakes to outright fraud and abuse.

Let me tell you, taxpayers, whether we are dealing with outright fraud or mere mistakes, neither helps to alleviate the concern and the pain of the taxpayers, who lose no matter how you look at it. Texas, unfortunately, has not been immune to the problems

associated with Medicare waste, fraud, and abuse. We have over 2.1 billion beneficiaries in our State. Medicare last year paid over \$12.7 billion.

The potential for fraud and abuse in Texas is very real indeed. While Texas and the rest of the Nation have been hit hard by Medicare fraud and abuse, I do want to commend the efforts of the Department of Health and Human Services in its Operation Restore Trust, a 2-year demonstration project, in which Texas was 1 of the 5 States selected to be involved.

Operation Restore Trust was kicked off in May 1995 to address the rapidly increasing costs in Medicare. It targeted home health agencies, nursing homes, and durable medical equipment suppliers in Texas, California, Illinois, Florida, and New York. Those States account for over 40 percent of the total Medicare expenditures nationwide.

Under Operation Restore Trust, Federal and State representatives, including HHS, the Department of Justice, the FBI, the U.S. Attorney's Office, State Attorney's General, and State Medicaid Fraud Control units, coordinated enforcement efforts to fight Medicare fraud and abuse. Because of this effort, more than a \$188 million has been identified as being owed to the Federal Government. This constitutes return of more than \$23 for every dollar spent. I applaud these efforts and everyone involved in this fight and I am very glad to hear that the project has been expanded into 12 additional States.

That said, I remain concerned about the Clinton Administration's efforts to fight waste, fraud, and abuse on all fronts. I am still concerned about HCFA'S failure to implement commercially available computer technology to detect improper claims and stop payments before they leave the Federal Treasury as opposed to the pay and chase method that Operation Restore Trust has used.

This committee has been actively reviewing the potential benefits of implementing commercial off-the-shelf software, commonly called COTS. The General Accounting Office has reported that it could save hundreds of millions of dollars annually in improper Medicare payments.

After resisting the GAO recommendation for years, HCFA, has undertaken a pilot project in the last couple of years to test this technology. Most recently, the committee's vigorous oversight efforts, which included a hearing on this subject this past September in Washington, insured that HCFA will conduct and continue to conduct this pilot program in a fair manner.

HCFA now estimates that it could save as much as \$465 million annually if it were to implement COTS on a nationwide scale. The new Administrator, who is with us today, and I have personally discussed this issue, and I believe she is committed to implementing this kind of software nationwide without undue delay if it's proven that it will save taxpayer dollars

As chairman of the oversight subcommittee, I am very proud of role that we have and our members have played in enacting tough new Medicare requirements as a part of the Balanced Budget Act of 1997. I, myself, promoted provisions in the BBA which set up a pilot program for competitive bidding for Medicare durable medical equipment and supplies. This means that there should be some new incentives to restrain the explosive

costs of Medicare. These changes should go a long way in fighting the waste and fraud that is currently plaguing the Medicare system.

I am aware, though, that there are concerns about some of these new provisions in our Balanced Budget Amendment and I am sure that those concerns are going to be brought out in the testimony of the witnesses that we have today. Both the home health care industry and Medicare beneficiaries are concerned, for example, with the surety bond requirement and also the provision on drawing of blood and the new prospective pay reimbursement system. It's my hope that information gathered here today will provide insight as to how the fraud and abuse provisions will interact, to actually save taxpayer dollars without imposing on quality health care.

I am very pleased to have with us today, Ms. Nancy-Ann Min DeParle, the newly confirmed Administrator at the Health Care Financial Administration. It means a great deal to me and to the subcommittee that she took time to fly down from Washington to be with us at our field hearing. She has asked in a hearing that we held in Washington not too many months ago to be held accountable. This committee will do that, but I must say that she is going above and beyond the duty to be accessible as we begin to work to be accountable. I know that she is equally as eager to root out the waste, fraud, and abuse that are currently in the system as any member of the subcommittee that's on the panel today.

I am also very pleased to have with us Mr. Paul Coggins, the United States Attorney for the Northern District of Texas, and Mr. Robert Richardson, the Assistant Inspector General for Criminal Investigations of the Department of Health and Human Services. Both of these gentlemen have been fighting Medicare waste, fraud, and abuse, and they both know the problems better than most in their area.

We will also be hearing from representatives of various industries to learn their perspective. For example, we will hear from Mr. Donald Chrysler, who owns a pharmacy and durable medical equipment business in Amarillo, Texas. We will also hear from Ms. Claudia Foster, who owns a home health agency in Waxahatchie. And Dr. Bohn Allen, who will give us a perspective from the Texas Medical Association on doctors' views. I will welcome all of our witnesses at the appropriate time.

Would the gentleman from Iowa, Mr. Ganske, wish to make an opening statement?

Mr. GANSKE. Mr. Chairman, I think the people of this community should be very proud to have such a lovely community center that we are in today. I think that government has a commitment that each person has a right to receive certain services to promote health, to correct the effects of illness or trauma, to carry on as many activities of their daily living as possible when confronted with chronic disease, to receive pain alleviation, and to receive comfort when they're dying.

I think our government also has a responsibility to a vision shaped by a realistic understanding of the resources available to a community and of the amount of those resources that society is willing to commit to the delivery of health care. That in a nutshell is the big dilemma that we are all facing when we are talking about how to deliver Medicare Health Care Services to the elderly.

Well, there is no question that we can do it better than we have done in the past. We are dealing with a \$200 billion a year program. The Congress and the administration have a responsibility to make sure that those hard-earned taxpayer dollars are spent on health care that's necessary for its citizens. So today we are going to hear, I think, some very interesting testimony on how to tighten up the program to try to control the abuse and to make sure that our citizens get the full value of the tax dollars that all the citizenry is providing for them. And I really look forward to the testimony from our HCFA Administrator, Nancy-Ann Min DeParle.

And also I have looked over, Mr. Chairman, the testimony of our second panel, and I think it's excellent in terms of some of the problems that we are going to have to address to make sure that government carries out this program better than it has in the past.

Mr. BARTON. Thank you, Congressman Ganske. I will point out that Congressman Ganske is a surgeon and has practiced medicine until he was elected to Congress 3 years ago. We also have with us Congressman Tom Coburn of Oklahoma, who is a practicing physician in Tulsa, Oklahoma, and was seeing patients this morning before he flew down to the field hearing Congressman Coburn.

Mr. COBURN. Thank you, Mr. Chairman. I just have a brief comment. The problems that we face in delivering health care through Medicare and Medicaid are never going to be solved until we change the incentives in the system. Where we got in trouble in home health care wasn't because people didn't want to do the right thing, but as they did the right thing oftentimes there were incentives to do a little more than what was necessary. And until we recognize that our health care in this country has to have incentives to do enough and not waste the resources of our children in the future, only then will we be able to solve the problems.

The Administrator of HCFA has an impossible job. The program is designed as it is today, it cannot be managed. It's impossible. So regardless of the quality of the people that are at HCFA, regardless of the situation, and until we change the program design, and change the incentives in the program in terms of financial, in terms of protecting what you do, when you do it, and how you do it, we will not solve these problems.

I think it is great we are having this hearing. It is interesting to hear the perspective from those away from Washington, and I am hopeful that we can learn. I think incentive in health care is the key to us solving our problems and rooting out fraud. There won't be fraud if we have the incentive to reimburse and properly care for those people that are depending on us. And I thank you for holding the hearing.

Mr. BARTON. Thank you, Congressman Coburn. Well, our first witness is already seated. It is my distinct pleasure to welcome to the subcommittee hearing, the Honorable Nancy-Ann Min DeParle, who is the Administrator of the Health Care Financing Administration. She has been confirmed by the U.S. Senate, prior to that she worked in the Office of Management and Budget as one of the Deputy OMB Directors.

Ms. DeParle, I think you know that it is the practice of this Subcommittee to take all testimony under oath. Do you have a problem testifying under oath?

Ms. DEPARLE. No, sir. I don't.

Mr. BARTON. I think you also know that the rules of the subcommittee and the Constitution of the United States, you have the right to be advised by counsel and any other technical representatives during your testimony. Do you think that you will need to be advised by counsel or need the advice of any of your technical staff?

Ms. DEPARLE. No, sir. I don't.

Mr. BARTON. Would you please rise then and raise your right hand and make sure the microphone is on. Please stand and raise your right hand.

Do you swear that the testimony you are about to give is the truth, the entire truth and nothing but the truth, so help you God?

Ms. DEPARLE. Yes.

Mr. BARTON. Your entire witness statement is included in the record. You are asked to summarize it. We will let you take such time as you may consume.

[The prepared statement of Hon. Nancy-Ann Min DeParle follows:]

PREPARED STATEMENT OF HON. NANCY-ANN MIN DE PARLE,

ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

INTRODUCTION

Chairman Barton, thank you for convening this hearing today to talk about one of my highest priorities as Administrator: combating waste, fraud and abuse in Medicare. It is a pleasure to be in Texas, a state which has been a pioneer in the fight against health care fraud.

Medicare has literally changed what it means to be old or disabled and sick in America. Over its 32 years of existence, Medicare has provided access to health care coverage for almost 80 million Americans, many of whom who would otherwise have lacked access to any kind of health care. And very importantly, Medicare is coverage that cannot be lost as you get older or sicker, or if you lose your spouse. Medicare has helped keep many elderly out of poverty status and prevented American families from having to bear the full burden of health care costs for their elderly or disabled parents or relatives. When President Lyndon B. Johnson signed Medicare into law, he predicted that Medicare would "take its place beside Social Security and together they will form the twin pillars of protection upon which all our people can safely build their lives and their hopes.

President Johnson was right. Today, Medicare is serving over 2 million residents of Texas, and more than 39 million beneficiaries nationwide. In Texas, Medicare spends

about \$11 billion each year, providing the State's elderly and disabled with over 3 million days of hospital care; 2 million days of skilled nursing home care; some 25 million physician visits, and providing home health services to about 260 thousand beneficiaries.

We are already achieving record success in increasing fraud and abuse investigations, indictments, convictions, fines, penalties and restitutions. Last year, using new Health Insurance Portability and Accountability Act authorities, nearly \$1 billion was returned to the Medicare Trust Fund, thanks to our partnership with the HHS Inspector General, Department of Justice and state and local authorities. Medicare alone saved an estimated \$7.5 billion in FY 97—mostly by preventing inappropriate payments—through audits, medical reviews, and ensuring that Medicare does not pay for claims owed by private insurers. Health fraud convictions are up nearly 20 percent and the number of civil health fraud cases increased 61 percent.

ON-GOING ANTI-FRAUD INITIATIVES

Operation Restore Trust (Restore Trust), launched by President Clinton in May, 1995, as a two-year comprehensive anti-fraud initiative in five key states designed to test the success of several innovations in fighting fraud and abuse in Medicare. The initiative focused on three specific areas: home health agencies, nursing homes, and durable medical equipment services in California, Florida, Illinois, New York, and Texas.

During its two-year, five-state demonstration phase, Restore Trust accomplished measurable successes: identifying \$23 in overpayments for every \$1 spent looking at home health care, skilled nursing facilities and supplies of DME and identifying 2,700 fraudulent health care providers and entities who were excluded from doing business with Medicare and other federal and state health care programs. Because of its successes, in May 1997 Restore Trust was expanded to 12 additional states and all Medicare service areas.

ORT In Texas

Our Dallas; Regional office developed an Operation Restore Trust management plan and has actively pursued fraudulent providers. The Dallas Office designed and implemented a number of projects aimed at reducing fraud, waste, and abuse in Medicare. One example is the Texas Home Health Survey initiative which proved to be one of the most successful in Restore Trust and has since been adopted as a fraud fighting tool by states across the country. As part of the project, the Dallas Office used existing relationships with the Texas Department of Health to have registered nurses conduct claims reviews as part of their regular quality of care reviews in home health agencies. Nurses, who visited home health agencies were given a sample of claims billed by the agencies and paid by Medicare. The nurses were asked to review those claims at the same time they surveyed the quality of care provided by the agency. The nurses looked for documentation to establish that all billed services were properly ordered and provided and that Medicare coverage requirements were met.

Since March 1996, 83 Texas home health agencies have been reviewed under this project with just under \$33 million identified in inappropriate Medicare payments. The most prevalent reasons that claims were denied were because the patients did not meet

Medicare homebound requirements, or the services provided to patients were not medically necessary. The project objectives and methodologies were distributed throughout central and regional Restore Trust teams and soon became the model on which other regions developed their own projects to survey home health agencies.

In addition, Restore Trust in Texas made national policy recommendations which HCFA swiftly adopted including: developing a statement for home health agencies to certify their understanding of the Medicare homebound requirements and revising manual instructions to include the definition of homebound.

In 1997, the Dallas office initiated a project to review physical, occupational, and speech therapy claims paid by Medicare for patients in skilled nursing facilities. The project adopted the process used successfully in the home health agency projects by combining the resources of the State Health Departments, the Medicare contractors, and the HCFA Regional Office. The overall objective of the project was to use the State Health Department's onsite visit to review a sample of claims Medicare had paid. Nurses looked for documentation that the billed services had been properly ordered and provided and that the services were medically necessary. The Medicare contractor reviewed the nurses' information and began seeking repayment for these inappropriate billings. In 1997, this project identified over \$400,000 of inappropriate payments made to skilled nursing facilities in Texas. In addition to recouping dollars, these types of projects prove the importance of partnerships between Federal and State partners to combat fraud, waste, and abuse.

Another Restore Trust project, directed by the HCFA's Dallas Office, identified inappropriate payments for durable medical equipment (DME) furnished to patients in nursing homes. All nursing homes in Texas are responsible for providing DME needed by their patients because payment is considered to be included in the rate paid to the nursing home. In cooperation with the State Medicaid Agency, and the Medicare contractor which processes DME claims, we were able to do identify separately filed and paid DME claims for nursing home residents for both Medicare and Medicaid. The project identified \$1.5 million in overpayments which has been recovered from the DME companies.

Anti Fraud Initiatives in Oklahoma, Louisiana and Arkansas

Building on lessons learned in Texas, our Dallas Regional Office has formulated fraud management plans for Oklahoma, Louisiana, and Arkansas where we have continued to crack down on those who wrongly take monies from Medicare. In Oklahoma, nurses from the State Health Department paid visits to 24 home health agencies last year where they uncovered just under \$1 million in Medicare overpayments. Working in conjunction with HCFA, nurses from State Health Departments visited skilled nursing facilities in Oklahoma, Louisiana and Arkansas to verify that speech, physical and occupation therapies that had been billed to Medicare were in fact provided and had been correctly billed. The nurses identified over \$1 million that was inappropriately billed to Medicare.

Working in partnership with the HHS Inspector General, the Department of Justice, and state and local authorities, we are achieving record successes in increasing fraud and

abuse investigations, indictments, convictions, fines, penalties, and restitutions. Our regional offices have been leaders in uncovering schemes used to steal from Medicare and developing initiatives for fighting them. In fact, the efforts of these men and women on the front lines have borne fruit in recent legislation, regulations, or other initiatives.

THE BBA AND RECENT INITIATIVES

With the support of many members of this committee, the Balanced Budget Act made the most significant changes in Medicare and Medicaid since they were enacted. We're already putting in place significant new tools to fight fraud, waste and abuse.

Among these are the authority to bar felons from participating in Medicare, require a surety bond of at least \$50,000 for home health agencies, durable medical equipment suppliers, and certified rehabilitation facilities, impose penalties for services offered by a provider who has been excluded by Medicare and Medicaid, impose penalties for hospitals who contract with providers who have been excluded from Medicare, require home health agencies to bill from the place the service was provided rather than from a more expensive central office and require health care providers applying to participate in Medicare to provide their Social Security numbers and their employer identification numbers so HCFA can check an applicant's history.

We estimate that a single provisions in the Balanced Budget Act which closes a loophole that allows home health agencies to bill in high cost areas will save the Medicare program millions of dollars in the state of Texas alone. A home health agency currently based in a metropolitan area of South Central Texas provides services to thousands of Medicare beneficiaries throughout that part of the state. Medicare reimbursement rates are driven by the cost of doing business in that community so reimbursements are much higher in metropolitan areas than in rural communities.

Although many of the Medicare beneficiaries are served by satellite offices of the home health agency in rural areas where the reimbursement rates for their services are much less, the company bills the services from the metropolitan office where the reimbursement rates are much higher. The Balanced Budget Act requires Medicare to pay for home health services based on where the service was provided rather than where the parent office of the home health agency is located. By closing this loophole, we estimate that Medicare will pay \$1 million dollars less for home health services in this one instance.

Home Health Initiatives

Over the last several months we have taken steps to make it tougher for home health agencies to enter and remain in the Medicare program. On September 15, 1997 the President announced a moratorium on all new home health agencies entering the Medicare program until HCFA could implement a range of new rules and management tools designed to enhance oversight of home health agencies and ensure that new Medicare home health agencies are not "fly-by-night or low quality providers.

The moratorium was lifted earlier this year with the publication of a regulation requiring all home health agencies that participate in Medicare to obtain a surety bond of at least \$50,000, reveal "related business interests" that often assist in fraudulent and abusive

activities, and serve at least 10 patients before they are admitted to the Medicare program after their quality of care is reviewed. Instructions have been issued to state survey agencies requiring that they must verify a surety bond and directing them to ensure a home health agency is serving its own patients and not those that have not been "borrowed" from an already certified home health agency. Furthermore, later this year HCFA will issue regulations to require home health agencies to re-enroll every three years,

DME Initiatives

Just last month we took additional steps to stop waste, fraud and abuse by illegitimate dealers of durable medical equipment (DME). HCFA has proposed a regulation to make it more difficult for unscrupulous DME suppliers to enter the Medicare program. Our goal is to make sure Medicare only does business with legitimate firms. In addition to clarifying the law requiring a surety bond of at least \$50,000, durable medical equipment suppliers will be banned from DME telemarketing, be required to have a physical location and a working business phone at that location be prohibited from reassigning supplier numbers, be held liable for criminal and civil sanctions for false information on billing number applications and will be required by regulation to re-enroll in Medicare every three years.

HCFA is also taking other actions to ensure that DME suppliers receiving Medicare billing numbers are legitimate. As the HHS IG has recommended, HCFA has begun requiring periodic training on billing procedures for new and existing suppliers and has modified the DME application form to obtain additional information about prospective DME suppliers.

Community Mental Health Center Initiatives

One of the newest and fast growing areas of fraud and abuse has been associated with Community Mental Health Centers. In January, we began a new initiative to stop the growing amounts of fraud and abuse associated with partial hospitalization services rendered by these types of mental health centers. In the last four years, there has been a dramatic rise in the total reimbursements, the average payment per patient and the number of mental health centers. Reviews conducted jointly with the HSS IG have revealed large scale amounts of fraud including services being rendered to beneficiaries who are not mentally ill by unqualified, unlicensed staff.

In an effort to ensure that only legitimate mental health centers are permitted to enter and remain in the program, HCFA will conduct onsite reviews of all mental health centers in nine targeted States, including Texas and Arkansas. We will terminate the provider agreements of all entities that do not meet Medicare standards. If this initiative proves successful, each fiscal intermediary will conduct onsite reviews of all new mental health center applicants, stopping illegitimate entities from gaining entry to Medicare and defrauding the Trust Fund.

President's Legislative Proposal and Other Initiatives

In January, the President unveiled a legislative package and several initiatives which give us new tools in our fight against Medicare fraud and abuse. The legislative proposals seek authority to collect a fee from providers in order to increase the number

of audits, eliminate wasteful excessive reimbursement for certain drugs, eliminate abuse of Medicare's outpatient mental health benefits, and prevent providers from taking advantage of Medicare by declaring bankruptcy.

These proposals will allow us to stop some of the unscrupulous home health agencies who have setup shop in Texas. In the early 1990's, a home health agency moved to Texas from the Midwest and started saving large numbers of Medicare beneficiaries. HCFA soon became suspicious of their large billings and with the HHS IG initiated an audit which found that the agency had wrongly billed Medicare for \$30 million. Before we could recoup these monies, the agency filed bankruptcy, discharging their debt and stopping our ability to recover these Medicare dollars.

The President also announced that HCFA has increased the number of on-site visits to DME suppliers. Operation Restore Trust initiatives have found many purported DME suppliers whose addresses are the sixth floor of a five story building or are only mail drops in places like laundromats and night clubs. Site visits to two thousand suppliers in five states with the most DME fraud problems resulted in 650 suppliers being cited or rejected by Medicare in FY 1997. Site visits began in an additional 10 states this month and will be expanded nationwide. These measures will make it more difficult for unscrupulous suppliers to enter the Medicare program.

Additionally, the President announced an unprecedented effort to involve Medicare beneficiaries in identifying waste, fraud and abuse. Over the next few months the Medicare toll-free fraud hotline—1-800-HMS-TIPS will appear on the statements beneficiaries receive listing the services that have been billed to Medicare on their behalf. Later this year, provisions in HIPAA will be implemented to give beneficiaries rewards for reporting fraud.

We simply cannot tolerate those who would cheat our beneficiaries and the taxpayers. That is why just last month I announced that Medicare will open an office in New Orleans that will coordinate anti-fraud activities in Louisiana. The New Orleans field office will open this spring. It's the latest step of the crackdown that President Clinton began in 1993. It will operate in the same way as our highly successful office in Miami. Medicare staff, based in New Orleans, will coordinate efforts among federal and state officials, law enforcement, private insurance and consumer advocacy groups. Working together, we will do an even better job of finding, prosecuting and preventing fraud and abuse.

Our experience with the Miami field office proved that onsite presence makes a considerable difference in raising public awareness of the Medicare fraud and abuse problems. The Miami office helped detect new types of fraud and proposed steps to stop it. We expect that this new field office too will make major inroads against fraud and abuse here in this region. Medicare beneficiaries of today and tomorrow deserve no less.

In the very near future, HCFA will publish a proposed rule which will allow us more flexibility in contracting with companies who can provide valuable services in the fight against waste, fraud and abuse. The Health Care Portability and Accountability Act provided HCFA with new authority to contract with private organizations to perform

program safeguard activities like audits and site visits. We hope to start enlisting these private entities by the end of the year.

National Conference to Identify Best Practice

In a few weeks, I will be convening a national conference to identify best practices in fighting waste, fraud and abuse. This conference will bring together about 200 representatives of private industry, law enforcement, health care providers, and beneficiaries to discuss what is being done to combat problems like credit card fraud, insurance fraud, and telecommunications fraud in addition to health care fraud. Representatives from our Regional Offices will also be present and following the conference will help design a long-range plan to guide the agency in fighting and preventing fraud, waste and abuse.

CONCLUSION

We have stopped a great deal of unscrupulous dealings over the last 4 years. However, the nature of health care fraud demands that we must continuously identify new measures in order to stay a step ahead of those whose intention is to misuse Medicare Trust Fund dollars. Each Medicare dollar spent fraudulently is a direct drain on the resources which provide health care for our nation's seniors. I hope to build on the growing momentum to ensure that Medicare Trust Fund remains solvent for generations to come.

As I said in my confirmation hearing, fighting fraud is a top priority for me. My tenure as HCFA Administrator will build upon the anti-fraud and abuse efforts that have already been initiated under the Clinton Administration. The Congress has provided the Administration with significant new tools in HIPAA and the BBA. Coupled with a number of new legislative proposals we are requesting for FY 99, we believe we have a strong new arsenal to remove bad actors from our rolls. I look forward to working with you in our efforts to stamp out fraud and abuse.

[Hearing Q&A]

[Bidding DME, surety bonds, financial accountability]

Mr. BARTON. Thank you. I thought when I gave you such time as you may consume, that you were going to consume more time. So you caught me preparing my questions. The chairman is going to recognize himself for the first 10 minutes of questions and then we will go to Dr. Ganske and then Dr. Coburn.

Again, I want to commend you for coming to Texas for our field hearing. As I pointed out in my opening statement, when you've got a program that is spending over \$200 billion, according to an audit last year, 14 percent of that is spent not on health care, so that is \$23 billion. We need to focus on this issue, and to your credit, you are.

One of the things that I did in last year's Balanced Budget Act was put in a provision, that was put into the law, that requires the Secretary of Health and Human Services to come up with a pilot program for competitive bidding of durable medical equipment. In our next panel, we are going to have a gentleman who is a durable medical equipment provider talk about some of the possible abuses in the current systems.

Have you had any interaction at all with Secretary Shalala about beginning to put together this pilot program for competitive bidding?

MS. DEPARLE. I certainly have. We did a briefing for her back in early January about our plans on it. She was very clear with me that she wants us to move ahead as quickly as we can on this competitive bidding demonstration, although there were a couple of steps that she wanted us to take before we actually announce it. One is to make sure that we briefed the Members of Congress in the areas that have been selected for this demonstration so that they're not surprised when they start getting calls about it.

Second, she wanted to be sure that we had a process in place to notify beneficiaries, because one thing that we have experienced in the past when we have tried to do some different things is that, you know, misinformation gets out, beneficiaries aren't sure what's going to happen, they get scared that they are going to lose their benefits somehow. And that is not what this is all about.

As you know, the whole idea is to see whether or not Medicare could go out there and try to look for the best price for the services that its beneficiaries need. We have not been able to do that. Under law, there are prices that we are required to pay. And that means that the Medicare program is paying for oxygen, for example, 2 or 3 times what the Veterans' Administration is paying for oxygen for its beneficiaries.

Mr. BARTON. Right.

Ms. DEPARLE. That is just not right, and it is not something that I can defend or you can defend. So, Secretary Shalala wanted us to be sure that we had a system in place to notify beneficiaries to make sure they were aware of what was happening before we went forward. I think we are going to be ready very soon. I hesitate to give a date because every time I do, I turn out to be wrong, but I would say when it starts looking this pretty in Washington, we will be talking about it.

Mr. BARTON. Okay. I am sure you and I will be talking about it.

MS. DEPARLE. We will be. We will be.

Mr. BARTON. Before it goes public. Another thing that I would like for you to address is also in the Balanced Budget Act from last summer which is the surety bond requirement for home health care providers. Here in Texas, it is been almost impossible, even for the excellent home health care providers, to get a bonding company willing to post bond. You are going to hear testimony later from one of those agencies about how difficult that has been.

Could you address the \$50,000 or 15 percent of a home health agency's annual billing requirement and could you also comment on whether any thoughts have been given to allow a review of the past records so that the home health care providers that have never had a problem perhaps wouldn't have to post quite so high of a surety bond?

Ms. DEPARLE. To just set the context a little bit, the reason why we have focused so much on home health in Operation Restore Trust, is because it is a benefit that over the past 6 or 7 years has been growing at a rate above 25 percent a year. And it is now at a point where we are spending about \$17 billion a year on home health services. The

number of services and visits per beneficiary has more than doubled in a several-year period.

There were lots of indications that the reasons for this growth were not all driven by the needs of beneficiaries. And, in fact, I think you made reference to two studies that have been done in the past couple of years by the Inspector General and one by the General Accounting Office. The Inspector General looked at, I think, five States including Texas and looked at the home health billings and concluded that about 40 percent of them were inappropriate, which I know from discussions with you is not acceptable to you and it is not acceptable to me.

So what we were trying to do with the surety bond requirement is to have some more requirements so that agencies who get into this business will be able to pay back Medicare should they get overpayments or should they have an instance of fraud or abuse. And also it has been shown that the surety bond will help to deter those who are just wanting to get into Medicare to rip it off from actually getting into the system.

Frankly, there weren't really any requirements or any hurdles that you had to meet at all. The new surety bond requirement went into effect January 1, we published around January 1, to announce the new surety bond requirement. Soon thereafter in talking to home health agencies and to surety bonds folks around the country, we discovered that there needed to be some clarification of our regulation, because it wasn't clear that the liability was limited to a certain period. Some of the surety bond companies were seeing it as an open-ended liability. And there were problems and you, yourself, called me about that to make sure I was aware that you were hearing the problems down here in Texas

So we announced that we were going to postpone the requirement and that home health agencies should request an extension. There are a number of home health companies who have actually been successful in getting surety bonds and it does seem like there maybe—

Mr. BARTON. Are you aware of anyone in Texas or Oklahoma, for example?

Ms. DEPARLE. I am not aware of Oklahoma, but our--one of our regional people did tell me that there were over several hundred. I don't remember the number in Texas, but several hundred. I think there are 1,300 or 1,400 home health agencies in Texas. So I think a couple of hundred, maybe, have gotten surety bonds, that is what I remember hearing a week or so ago.

But in any case, we have postponed the requirement for basically 60 days to make sure that we can clarify the requirements for the surety bonds and get the word out there so that folks won't have so much trouble. I should say, though, that there are going to be some companies who will not be able to get surety bonds. And the reason is that, as was the experience in Florida which has instituted this requirement on a State basis, there are some companies, when you look at their records and their backgrounds, that a surety bond business will decide is too risky of a situation. Maybe they've had a lot of overpayments, maybe there have been some abuse problems in the past. So we don't expect it to be the kind of thing that a reputable agency would have a problem getting

and we want to continue to work with you and your committee on making sure that that happens.

Mr. BARTON. Well, that is something we are going to have an ongoing dialog on because again, I support and I think the majority of Congress supports that there needs to be some financial accountability. But we don't want to make it so restrictive that home health care providers that have never had a bad audit or never had a problem end up not getting a bond or going out of business. We don't want to leave the fly-by-night people in business and--

Ms. DEPARLE. No.

Mr. BARTON. [continuing] drive the good ones out.

MS. DEPARLE. That is not the intent.

Mr. BARTON. I have got time for one more question, I believe. The Commission on the Future of Medicare is scheduled to meet for the first time next month or this month. Could you discuss how you plan to interact with the Commission to help develop ways to strengthen and improve Medicare for the years ahead?

Ms. DEPARLE. Yes, sir. We look forward to working with the commission and providing technical assistance and analysis and support in any way we can. We frankly have our plates full at the Health Care Financing Administration right now, not only with trying to do better on fighting fraud, waste, and abuse, but just implementing all of the different provisions of the Balanced Budget Act

And I feel like that has to be my top priority because in enacting the Balanced Budget Act, you extended the solvency of the Medicare trust fund by 10 years, which is a very significant achievement and it is against that backdrop that the Commission has the breathing room to do the kind of work that it needs to do. But we have to make good on the promise of extending the solvency of the trust fund. If we don't get the provisions of the BBA enacted, you know, it won't be there. So I feel like that has to be our first priority. But I stand ready to work with Congressman Ganske and his colleagues on the Commission in any way that we can and especially in providing analysis and data about Medicare and its programs.

[Proceeding to the testimony of Paul Coggins]

TESTIMONY OF PAUL COGGINS,

UNITED STATES ATTORNEY FOR THE NORTHERN DISTRICT OF TEXAS

Mr. COGGINS. Thank you. Is that—do I need to hold this to talk?

Mr. BARTON. Yeah, I think so, but it's working.

Mr. COGGINS. Thank you for your invitation to appear here. First I'd like to say, I am the U.S. Attorney for the Northern District of Texas. The Northern District of Texas

encompasses a hundred counties in North Texas. It includes four of Texas' ten most populous cities and a hundred of Texas' hundred most beautiful counties.

On the health care fraud enforcement today, I'm going to be talking to you about civil enforcement and criminal enforcement. And I'd like to start out by saying that recently Congress, the administration, made more resources available to the Department of Justice to fight health care fraud in the 1996 Act. That has made a big difference in our effectiveness in fighting this problem. And behind me in the audience is Pete Winn who worked predominantly in civil health care fraud enforcement. Pete was hired by our offices pursuant to funds made available in the 1996 Act.

Until recently, health care fraud was the most under investigated, under prosecuted area in white-collar fraud. The Department of Justice followed a two-pronged attack which includes not only enforcement but also pushing compliance programs to avoid the necessity of enforcement actions.

On the civil enforcement, our actions are generally brought under the False Claims Act. The False Claims Act only covers false claims that were done knowingly or with deliberate ignorance or reckless disregard of the falsity. And it is important to note that the False Claims Act covers far more than health care fraud, for example, it covers defense fraud as well. And in all cases whether—in all cases, the burden of proving the false claim was done knowingly or recklessly falls upon the government.

Under the False Claims Act one of the cases we're going to need to talk to you about today involves a recent settlement our office entered with Pro Med Pharmacies for approximately \$1 million. Pro Med is headquartered in Amarillo, Texas. I'm glad that Mr. Donald Chrysler will be here to talk about that to you.

Pro Med was involved in paying kickbacks to durable medical equipment companies for patient referrals. Kickbacks have been a serious problem we have uncovered in our health care fraud investigations because they drive up the costs of goods and services and because they harm the individuals and companies that play by the rules. Our investigation determined that Pro Med did not begin the practice of paying kickbacks, but felt that it had to do that to compete with others who were doing so. The amount of the settlement reached with Pro Med represents roughly two times the kickback payments and the cost of the investigation. And one of the things that Mr. Chrysler and I are here to tell you is the absolute importance of having a level playing field in the health care fraud area.

Another important investigation our office worked on with a number of other offices involved National Medical Enterprises, that was a national investigation involving a chain of psychiatric hospitals in North Texas and elsewhere. The investigation uncovered kickbacks for patient referrals and a series of false claims.

We've had a number of convictions in this district of doctors and others in the health care area and sentences ranging everywhere from probation to 8 ½ years of prison. In addition, NME reached a settlement with the Department of Justice in the amount of approximately \$370 million and equally importantly entered into a corporate integrity plan which was one of the first of its kind.

One of the important points I'd like to make about the False Claims Act is that it does not cover, it does not extend to honest mistakes or even to negligence. And if a provider believes that it has been, it has made such an honest mistake or it has been negligent, it will have a chance to make that case before suit is filed. In my office, the United States Attorney's Office of the Northern District of Texas, we have an open door policy and in every one of these cases it benefits us to hear the other side before spending a lot of time and effort filing a lawsuit. But having said all that, our system presupposes that the provider will accept responsibility to ensure the accuracy of the bills being submitted.

A couple of representative criminal prosecutions we've had in the Northern District of Texas include one of a podiatrist, who basically mis-described routine nail trimmings as nail avulsions and debridements in order to bring its coverage within Medicare. In addition, we've had a home health service which fabricated documents to the tune of about \$500,000 which included ghost employees.

Fighting fraud in the Northern District of Texas has been a major priority since I became the United States Attorney in 1993. In 1994, we founded a regional health care fraud working group and one of the things we did was meet with private companies to determine the scope of the problem and the type of the problems we were having in the Northern District of Texas, we exchanged information. Because of the success of that working group, in 1995, we established a Metroplex Health Care Fraud Task Force which now has 18 agencies participating. We have approximately 90 ongoing health care fraud investigations in our office now.

We have two exploding areas that have already been touched upon, I've run out of time. I don't need to belabor the point, but obviously, they involve home health agencies and durable medical equipment agencies. Health care investigations and prosecutions are time consuming, they are personnel intensive. The cost of the crimes include higher insurance premium and higher taxes. They, of course, divert their sources away from those most in need to those who are willing to break the rules.

We all have a stake in preventing health care fraud where we can, cracking down on health care fraud when necessary, and no one more so than the vast majority of honest doctors and honest providers out there who want to play by the rules. I welcome your continued interest in this problem and your help in our addressing

Mr. BARTON. Thank you, Mr. Coggins. Let's set the clock for 7 minutes. I think 5 is too little.

TESTIMONY OF CLAUDIA FOSTER, ADMINISTRATOR, ASSOCIATED HOME HEALTH CARE

[The prepared statement of Claudia L. Foster follows]

My name is Claudia Foster. It is my pleasure, my privilege, and my honor to provide what I hope to be a "real life" testimony from small town America.

I am a mother, wife, Republican baby boomer, and the owner of "one of those deplorable home health care companies"—you know, the ones that are stealing Medicare money! And yes, my credentials more than qualify me to be in this position. While I will not try to fool you into believing that I know everything about home health, I will tell you that I am an authority on the differences between what is morally and ethically right or wrong. I do not lie, nor will I color my testimony to try to make a name for myself. I could care less about anything except the elderly people that I represent, and my company that allows me this privilege. Just for your benefit, please note on my resume that I became a gerontologist long before it was fashionable to take care of senior citizens.

Now, let me warn you that the following testimony is intended for mature audiences—audiences with the guts enough to hear the cold hard facts. If any of you present here today cannot face the truth head on, then I suppose you should ask me to excuse myself.

The reason that I am here today is because of 4 words that crawl under my skin like a cancer: Medicare Waste, Fraud, and Abuse

Relax I am not guilty as most home health agencies have been charged, and don't look to me for any "true confessions". The only thing that you will be able to accuse me of is managing Medicare dollars with honesty and integrity. The only thing that I am guilty of is putting up with far too many bureaucratic rule changes that leave vulnerable senior citizens right in the path of the storm. Now, I realize that HCFA has a job to do, and so do our intermediaries, but for God's sake, could they please come out from behind their desks for a moment and follow me into real America? In fact, I'd be happy if they could just agree on something as simple as whether or not a patient qualifies for home health. (refer to Feb. 10th Home Health Line, page 3 and 4)

Could you, our elected officials, and someone from HCFA please listen to those of us that walk the streets of real America? Could you please think about me before you put rule making in the hands of an entity whose life is not directly affected by a system or a bond that make it impossible for me to survive?

Now wait a moment! Don't even begin to think that I am some air-headed female about to give you another gut wrenching scenario of patient "x" who cannot get into a car to have blood drawn at the lab. I agree with you that aide visits for venipuncture patients were in some cases, out of hand. But did we need to throw the whole shooting match out of the window?

I am not stupid enough to believe that fraud and abuse do not exist nor do I believe that agencies are not over-utilizing services. I am telling you that fraud does exist and I'm saying that along with you, I am damn angry about it. It happens in small town America; even in Waxahachie Texas. I see it alive and well and growing at alarming rates. But guess what else my eyes are telling me: I see a system that was not set up to handle a problem of this magnitude, and now I find myself looking for someone to take accountability for this cost-reimbursement mess that I find myself in today. I just can't get anyone to own up. Once again for my good old system, I, or shall I say we, have become scapegoats. Reputable home care agencies with a conscience are bearing the

brunt of upset beneficiaries, and are terminating superior staff members because of crippling cost limits.

Would you like to know what you'll have left to deal with? What you will be faced with when good little Claudia Foster shuts her door is the other kind of agency that has chosen to ignore all of the information about the Interim Payment System surety bond, or cost limits. This is the agency that stays in business by being around to admit patients that my rule abiding company discharges, because they no longer qualify for care. (By the way, their bills continue to get reimbursed. Why is this?) This agency would probably accuse me of patient abandonment, and I in turn would say nothing because I have far too much class to stoop to arguing with anyone who doesn't know the difference between doing the right thing, and cheating. So I ask you—has our "new system" handled any waste and abuse? I don't think so!!! Don't tell me that it hasn't had time to work. Crooks don't need time.

I would feel a whole lot better if someone higher up than myself would just acknowledge the fact that a mistake was made, and that something must be done to stop the madness, before another senior citizen has to move into an institution. After all, our nation's elderly, are more important than my personally being able to survive what I will come to label as "The Home Care Crash of 1998". You see I have nothing to lose here today. My company is near death and it will not take long for me to find an appropriate place for my talents. I have nothing to lose by telling the truth, no matter how much it hurts, or no matter how angry it makes anyone.

[Cost Reimbursement System-Problems]

Let me explain why we are in this mess today. A cost reimbursement system provides an open invitation for misuse and mismanagement. It is not necessary to work at being efficient—our costs are paid... period! The regulations presented in this cost reimbursement climate allow for various approaches of interpretation. At this point in time we have put an impossible task in the lap of the Health Care Financing Administration by asking them to give us a quick-fix payment approach, when in actuality, a problem lies with open-ended, unclear regulations, which ends up leaving interpretation in the eyes of the beholder. I challenge you to take a regulation, put it on the desk at HCFA, an intermediary, an agency, and a home-care nurse, and you will receive 4 different explanations. Whatever happened to rules written in black or white, a given right or wrong, and a consequence for breaking them?

I need to take a deep breath for a moment and tell you as respectfully as I know how, that all of the measures currently being taken to rid us of system abuses are in and of themselves, creating more chaos that any of us are equipped to deal with.

[Problems with Surety Bonds]

I go on record today as telling you that I will not sign any surety bond, which holds me personally and financially accountable. The cost based reimbursement system governing my home health agency will not allow the establishment of any equity. Why do I want to place my life's earnings and my children's future at the hands of some bad mood wedge auditor that may decide to interpret something in my chart as fraudulent? Remember? No black, no white means an interpretation based the auditor that you happen to receive. The dollar amount of the surety bond for Associated Home Health is valued at \$350,000. Since Associated is allowed no equity, the insurance company will

not write the bond for my agency. In order to secure it, I must personally guarantee 10x the bond value in assets which calculates in at approximately \$3.5 million dollars.

Forget it. I won't do it. Better yet, why should I be made to post the surety bond when Medicare has had no problem recouping any overpayment from me in the first place? (see exhibit). On May 1, 1997, I received notice from my accountant that my cost report reflected a payable to Medicare of \$95,817. On May 30, Medicare was issued a check in the full amount. How 'bout them apples? Surety bond you say? Don't even go there with me.

Now I ask you, If my visit numbers in Texas are so out of control, why do my claims get paid? If I am so abusive of the Medicare system, how do you explain that I have received zero deficiencies on my last three state surveys? I have only done what I was trained and allowed to do by my intermediary and HCFA.

[Error triangle; HCFA, Intermediary, Provider]

These questions are leading me down the following path:

We have all become part of a mistake triangle: HCFA at one point, the intermediary at one point, and provider at one point. The blaming game will not solve anything. It is time to seek out another solution. I will offer today to volunteer my time and expertise to team with HCFA and my intermediary, and will offer any amount of hours needed to help get this system straightened out. The voices that need to be represented are the ones out in the field providing a life line of hope to ease the institutionalization fears of our elderly. Our nation's elderly if given a choice, want to stay at home, yes, at home.

Congress, do not let HCFA continue to waste time on finishing and implementing IPS. We need them to spend this time revamping coverage guidelines and give us concrete rules in black and white, with definite, harsh consequences for deviation from them. The color gray will not cut it anymore. The quick-fix approach of IPS has a strangle hold on my company and hundreds of others as well. I will not be left to work under a Prospective Pay System. IPS has killed Associated, and that is a tragedy for my community. Don't feel sorry for me though—I am a big girl. Feel sorry for the patients and physicians that I can no longer serve. At this point, it is too late for HCFA to send me anymore threatening letters about how I explain Medicare payment reform. My patients have been well informed, and truthfully informed as the Medicare conditions of participation require. My patients know exactly where the ball began its bounce. There is no way that anyone will threaten me against telling the truth.

In conclusion of my testimony today, I leave you with the following:

When I despise things that are terrible, and then stand my ground against them, I become brave.

NOW, to you my elected officials, and to you Nancy DeParle, I offer you the keys to Associated Home Health along with my resignation, in the hopes that you can figure out a better way to keep my home health agency alive. Good luck, and by the way, the Agency will no longer be able to afford your salary.

[Hearing Q&A]

[Improper payment, safe harbors, financial accountability]

Mr. BARTON. Thank you. The chairman is going to recognize himself for 10 minutes and then we'll recognize Dr. Ganske and Dr. Coburn. Unfortunately, we're only going to have time for one round of questions because it's already 5:15, but there will be additional written questions that we will submit for the record.

The first question I have is to Mr. Richardson. I had a home health care provider come up to me at the break and accuse me of stacking the deck; which is hard to believe after Claudia Foster's testimony and Dr. Allen's testimony, but so be it. But one of the things I was asked was about this number that we had at our hearing about 2 or 3 months ago about 40 percent of waste, fraud, abuse, and home health care claims.

Do you want to elaborate on that and on the study that came out last July based on records that were looked at from several years before that. Do you have any additional information you'd like to enlighten us with about those studies or any studies that have been done subsequent to that?

Mr. RICHARDSON. I am familiar with the studies—the studies were limited to a group of States that had a disproportion—or that represented a disproportionate number of our Medicare beneficiaries. Operation Restore Trust looked at five States, those five States had 40 percent of the beneficiaries. The study that you're referring to was a selected sample. One can certainly argue that the sample might not be indicative of small town America. I would be the last person to be-- to argue that it is. *But in the home health agencies* that we've reviewed, 40 percent of the payments were inappropriate.

Mr. BARTON. So that's a number as far as you know that the Inspector General at HHS have not backed away from.

Mr. RICHARDSON. That's correct. We have not backed away from that number.

Mr. BARTON. Mr. Chrysler, you've talked about a system in durable medical equipment and pharmacies where, I don't think you said this explicitly, but you basically feel like to stay in business you were forced to do something which the Justice Department is now signaling as illegal. That you fought against it, but in order to stay in business you decided to do what everybody else was doing.

How could we change the system so that the problem that existed with you would not be a problem any longer? That you wouldn't have to pay referrals.

Mr. CHRYSLER. Well, what I feel like the problem was, was the ambiguity of the law. I think there's more than one legitimate interpretation of what the law says. And in the-- with the lack of direction from—from the government to what their interpretation is going to be, the industry was left to interpret the law for themselves basically.

Mr. BARTON. But now do you feel that it should be legal to pay to get a referral and then basically charge the taxpayer for that?

Mr. CHRYSLER. No.

Mr. BARTON. No. So that's—now correct me, I'm not trying to put words in your mouth, but apparently that's what was happening. So I'll ask Mr. Coggins if he wants to comment on how to change the system. As the real world person I want to give you a chance.

Mr. CHRYSLER. Well, their safe harbors were written to help give guidance with respect to the Medicare anti-kickback statute. I don't think—I think the safe harbors need to go further in their explanation and—and—

Mr. BARTON. Let me just throw some possible solutions at you. What if we required transparency so that potential customers were available to anybody who wanted to look on a web site on the Internet or posted in the Federal Register so that, you know, the patient—the potential patient group was not a commodity—that only one company had access to that would be one thing.

Another thing would be to go to some sort of a competitive bidding situation where you priced the market instead of priced according to some fee schedule that was based on a regional price survey. I mean, if those two things were in existence, I don't think your problem *would have* occurred.

Mr. CHRYSLER. That may have some possibilities.

Mr. BARTON. So that's something you'd be willing to look at.

Mr. CHRYSLER. Yes.

Mr. BARTON. Mr. Coggins, you're aware of this case. It's been settled, so obviously, you can talk something about it. What would your proposed solutions be to this particular issue?

Mr. COGGINS. I think one of the things that did happen is that Congress created the opportunity for advisory opinions in certain areas. And that's an option that's open, I think. HHS can provide advisory opinions on what you can or can't do. I think the general principle is pretty clear. You can't pay a kickback, as you said, for a patient referral and then you have a question of what constitutes a kickback. Was it a kickback? Was it a disguised kickback?

One of the things I would like to address because Mr. Chrysler has been very forthright in dealing with our office, very forthright in coming here and talking this when he didn't have to do it. Is that we feel the key thing for most doctors and most providers, as I said, they want a level playing field. They want to be given a chance to operate within the rules and make sure others are operating within the rules. And if that's going to happen, we're not going to be able to allow kickbacks to occur in this system, because the only thing a kickback system will do is raise the cost of goods and services for everybody. It's going to cost taxpayers more money and the insurance companies more money in the long run.

Mr. BARTON. All right. Ms. Foster, you were fairly eloquent in your testimony about what you're not going to do, and I don't blame you, but you also admitted that there's a

problem. Now, I think that it's appropriate that there be some financial accountability for health care providers.

Ms. FOSTER. I agree.

Mr. BARTON. And I think that it's appropriate to have some sort of surety bond. I'm with you on the issue of 10 times the personal liability. So give me a potential solution that we can work with HCFA and HHS. I mean, how do you get to where you want to be?

Ms. FOSTER. I'm not sure I have a solution for the whole big picture, but I do know that those of us that have done the right thing should be allowed some leniency.

Mr. BARTON. So one possible alternative is to look at your past record, if you have a record, and if it's a clean record, not have quite as high a bonding requirement; would that be a possible solution?

[Surety, Payment Methods]

Ms. FOSTER. I'm not at all opposed to a bond. Personally, I would like to see a lot of agencies out of business because a lot of those agencies are thorns in my side.

Mr. BARTON. Now if—we've got a representative, not the panel, but in the audience, from surety bond companies, and that representative have pointed out there have to be assets which can be pledged against the bond. If you're in a situation where by law you're not allowed to maintain equity in the business, how would you calculate the size of the bond or would you not even try to calculate it based on your business, simply calculated it based on your past practices of compliance? You understand the question?

Ms. FOSTER. I think so. I'm not certain and Mr. Singer can help me with this, when we do go to prospective pay, will we at that point be allowed to have equity in our business? We will. So the problem really is between now and October 1, 1999.

Mr. BARTON. Now in terms of the interim system, the interim payment system, I've looked at it, I'm not in the home health care industry, obviously, but I've looked at it, and I think that it is an attempt to be fair in the transition to the full prospective payment system. Do you have things that you wish to put in writing on the record, maybe not today, but before we issue our final report about how you might want to fine tune this interim payment system? We have to have some way to get away from the open-ended system we have today.

Ms. FOSTER. SO you're asking me for suggestions and possible solutions?

Mr. BARTON. Yes, ma'am. I'm allowed to do that as the chairman of the committee. I can ask for solutions.

Mr. GANSKE. It's just not done often.

Mr. BARTON. But you don't have to give them to me right now.

Ms. FOSTER. That's what I wanted to hear. If I don't have to come up with it today.

Mr. BARTON. That's the purpose of these hearings.

MS. FOSTER. I'll come up with something, I promise.

Mr. BARTON. You know we don't have a predetermined point of view. We actually, believe it or not, want to hear the truth and then try to make good policy based on what we think the truth will be

MS. FOSTER. I'll come up with something I promise. And all I'm concerned about is keeping the doors of my company opened and at the rate we're going it's looking bleak.

Mr. BARTON. I understand that. The chairman is going to recognize Mr. Ganske for 10 minutes.

Mr. GANSKE. Well, first of all, Mr. Chairman, I want to thank you for having this hearing. I've learned a lot and I think that everyone here has probably learned some very interesting things.

There's a pretty large home health care contingent in the audience, I can tell. So I want to share with you the inside skinny of what went on with the Balanced Budget Agreement because you may not hear this from your lobbyist in Washington, but this is what happened. When we were looking at home health care costs and trying to get a handle on this, there were basically two ways to develop changing policy.

One would be to set up a co-payment for home health care. The proposal, in fact, I think Ms. Foster, you've told me personally that is something you would not be opposed to. And there are some in the home health care industry think that would be a good idea. But the home health care industry lobbyists put an absolute nix on that idea.

This was your representatives representing you in Washington saying, "No way, Jose," to that idea. So what was the alternative? The alternative was a prospective payment system similar to what the hospitals function under, guidelines as to related improvements. So that's what the agreement came to be.

The administrations—now listen carefully to this—the administration's interim system proposal that we've been talking about would have based the cap on 100 percent of an agencies' historical cost updated for inflation. That's what the proposal was in the negotiations.

However, your representatives were concerned that that would reward the high cost provider and lock in the low cost providers. I'm sensitive to this problem. I understand why the health care industry decided not to go with a historical basis only for an interim prospective system. It's because how many of you—how many of you are with the Visiting Nurse Association [VNA]? Is there anyone here? There's a couple in the back.

Okay. Well, in Iowa, for instance, the VNA's have offered, I think, pretty efficient home health care at lower costs than some of the other agencies. They felt, and their voice was heard within the home health care industry, that if you use only a historical basis for the transition, that those agencies which have been cost efficient would be penalized. While those that have had higher costs would be benefited. This was the argument from

the home health care industry lobbyists. We don't want a purely historical basis, so what came out of it?

A compromise was reached that blended the cap, 75 percent agency specific and 25 percent regional, to take into account differences from around the country. Within each region the blending will increase the cap for agencies that were below the regional average and it would decrease somewhat the cap for the agencies that were above the regional average. That was what your industry agreed to.

That's why the law is the way that it is. Because we recognized that if you're not going to go to a copayment system and you're going to go to a prospective payment system while you're developing the data, you've got to have an interim system. That's the facts. Now, there are some industry representatives who are proposing their own prospective payment system right now. They claim it's ready for immediate implementation, but we looked at that proposal. We did a detailed analysis of that proposal and there were some real problems.

The system is built around "bonus payments" to home health agencies. That system would reward agencies that avoid the sickest patients and skimp on the care that they provide to their patients. That's a real problem. So I think that it's useful for people who are involved in home health care to have an ongoing dialog with HCFA, but it's also very important for you to understand the background of where we're at this particular moment in terms of this interim payment system.

[Knowing and willful]

Maybe this is something that the Medicare Commission will look at. I don't know, we will hold our first meeting this week. And I'm on it and so, I think it is an important thing. I've worked a lot with people who-- personally with people who provide home health care and it's a necessary service that we want to do right.

Now, with that brief statement I just want to finish—I just have one question because Mr. Chairman, both Congressman Coburn and I have to catch airplanes pretty soon. But this isn't just for home health care, it's also for other providers.

I'd like Mr. Coggins to address the question about, you know, you're the U.S. Attorney. You're the guy that's going to have to interpret and look at this fraud and abuse problem. In the legislation that Congress passed, there is a provision that calls for **knowing and willful violation** as a burden of proof on the government in terms of proving fraud and abuse.

I think it would be very important for the people in this audience to hear how you as the U.S. Attorney interpret those two words and if you could expand on that to inform me and to inform the members of the audience exactly how you're going to go about looking at these provisions. Because we've heard an awful lot of fear, I think, in this audience that, you know, somebody makes an honest mistake and they're going to have the force of government ramming them up against the wall. I wonder if you could address that.

Mr. COGGINS. I'd be happy to because knowingly and willfully are basically two words that are used in almost all provisions whether it's medical or other types of cases we do. It is an element of proof that we have to address and it's put in the statute to weed out

two things; to weed out, as the Congressman mentioned, inadvertent billing errors, and everybody that's been in practice.

And I can promise you this, I wasn't a bureaucrat my whole life. I spent 10 years as a lawyer in private practice. And if you combed over every bill I sent over 10 years and I had to swear I never had an incorrect bill, no one could do that. We understand that. So it's to windle out inadvertent billing errors or even negligent billing errors. Because negligent billing errors are not the subject of either criminal or civil cases under the False Claims Act or other criminal statutes.

But it is important to know that in every case those words are a burden upon the government whether we're talking a civil case or a criminal case. And we have what I call an open-door policy in my office, which means that we try to give notice before we're going to take any kind of action to give our representative a chance to come in and say, "Hey, you got it wrong here. What you thought was a fraudulent scheme is not a fraudulent scheme. What you thought was disguised kickback was not a disguised kickback."

[Industry feedback, Government responsiveness]

Having said that, most cases that we end up taking in our office are made not through an audit quite frankly, particularly the criminal cases, most are made by whistle blowers inside a corporation, inside a provider, who come to the government and say words to the effect that, "We have a service that was not covered by Medicare and we were instructed to change the code and file it some other way or we were told to bill for services we never rendered." Those are clear cases where you're talking about actual knowledge of a criminal act.

So, bottom-line, one of the reasons we formed our working group is to get feedback from industry representatives just as the Congressmen are here today. I try to make myself, I try to make Peter Winn of my office, available to industry groups that would like us to talk to them and we will make that standing offer to anybody here today, that if you get us a card and you want us to come out and visit with you and to understand and to walk into that small town with you and see what you're facing, we will be happy to do that and look forward to doing that. Because I recognize, as I said in my testimony, nobody has a bigger interest in cleaning up the system than people who are trying to operate honestly within that system. That's true whether you're talking about medical system, whether you're talking about banking, or any other system. And that's what we're trying to do. Our resources are so limited in here we're going to have to go after the people who deserve to be put out of business and keep the people who are doing good jobs in business. Thank you.

Mr. BARTON. Dr. Ganske, did you want to have one final moment? For the final 10 minutes of questions, Congressman Coburn of Oklahoma

Mr. COBURN. I won't take 10 minutes. I want to get on my flight. Mr. Coggins, what you said about your office is great, but I want to tell you, not every U.S. Attorney has your attitude. And that's one of the things providers whether home health, or CME providers, they don't have that ability and I'm sorry Ms. DeParle left today, because one of the things she needs to hear is that you ought to have the ability in this country to be able to

ask the government if what you're doing is right or wrong and then tell you rather than say, 'We don't have to tell you. Try it and then we'll see.'

We can change that. That's something that I'm sure most people would like to see changed. The reason it's not there is because what I said earlier about HCFA. It's an impossible set of tasks that we've asked them to do and so what we have to do is work toward it. I promised some home health people that I would ask this question. I want to ask this even though Ms. DeParle is gone. If you work for or are associated with a home health firm or are a lobby for that, would you please stand up.

Now, if your firm has a surety bond, stay standing. If you don't, sit down. Okay. So there are a significant number as Ms. DeParle said. Thank you

Mr. BARTON. Ask if they all work for the same company.

Mr. COBURN. Do you all work for the same company? Yes.

Mr. BARTON. There are one or two women who weren't.

Mr. COBURN. I want to say something to Ms. Foster. I listened with interest to your spunkiness. You reminded me of myself in Congress, which means you're going to get in trouble, but I tell you you're exactly the type that shouldn't quit. And if you say to HCFA, 'No,' then what happens is, is we're not going to change our government. It's only when you come to an interface with our government when you know it's wrong, you can't quit. That's when you dig in and try to change it harder.

And my comments to you are, is don't back down, don't change, stand there to toe to toe, and get it changed to where it's acceptable for the reputable firms.

Ms. FOSTER. Well, can you promise me that that could happen?

Mr. COBURN. No, I can't promise you anything. I'm a politician. Don't you know? All I can do is promise I'll be here for your delivery. Actually what you have to know is that, people like you quit, we lose. We all lose. The seniors lose. We lose as Members of Congress. Joe loses, HCFA loses. We have to fight.

The job that we all do every day is against the tendency for the government to take more of our freedom away. And when you express what you've expressed today, what you're saying is you're going to let them take more out of it. And what I want to leave you with is, you have an obligation to everybody else that's involved in this health care to not quit, to change the system. I'm glad you're here and I want to encourage you to do that. And I'm on the way to catch my flight, Mr. Chairman, thank you.

Mr. BARTON. We're going to submit written questions for the record for this panel. I'm sorry we didn't have a second round, but we will have some written questions. I want to thank the city of Colleyville again for letting us use their facility as well as Dr. Coburn and Dr. Ganske for coming. Congressman Klink and some of the democrats couldn't come, but Congressman Klink had a death in the family.

We're going to do other hearings on this in Washington. We'll probably do other field hearings around the country. And as we've all tried to indicate, we're trying to find out what the issues are so that we can quickly move toward solutions. And especially those in the private sectors, your testimony is very, very helpful in that regard. This subcommittee is adjourned.

Whereupon, at 5:47 p.m., the subcommittee was adjourned.

[Follow-up written Q & A]

[Additional material submitted for the record follows]

DEPARTMENT OF HEALTH & HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION
May 12, 1998

The Honorable JOE BARTON
House of Representatives
Washington, D.C. 20515

DEAR CHAIRMAN BARTON: Thank you for holding the House Commerce Subcommittee on Oversight and Investigations March 2 field hearing on fraud, waste, and abuse. Fighting fraud, waste, and abuse is one of our highest priorities, and I greatly appreciate your interest and support in this effort. This letter includes the responses I promised for the record at the hearing, as well as responses to the letter you submitted from Representative James C. Greenwood with additional questions for the record.

Timetable for Centralized Claims Depository

You asked for a time frame of when we might have a centralized system that will allow us to make sure we are not receiving claims on the same patient from multiple Parts of the country simultaneously. Medicare's existing Common Working File does have some capability to check for duplicate claims. The feature is used to check for duplication on every claim for durable medical equipment and on a sample of other types of claims. Improving the system is a high priority, but as you know, modernizing the Health Care Financing Administration's (HCFA's) computer systems has proved to be more challenging than we expected.

Our hopes for the Medicare Transaction System (MTS) were not realized, and we have learned the hard way that an incremental approach is best. Currently, our top priority is to ensure that all HCFA contractors and subcontractors have computer systems ready for the Year 2000. This is a daunting task, and until it is complete we cannot accurately gauge when we will be able to bring other necessary modernizations on line. HCFA is mandating that all contractors be in full compliance by December 1998, so we will have a full year to test the system to remove any remaining bugs.

At this point, a centralized claims depository will have to come after Year 2000 issues are completed.

Physician Accountability for Home Health

Representative Coburn asked about a provision of the law that holds physicians liable for the home health services they order. This provision, that was included in the Health Insurance Portability and Accountability Act of 1996, will allow the Department of Health and Human Services (DHHS) Office of the Inspector General to impose civil monetary penalties on physicians for improper certifications. I am happy to report that the Inspector General's office published a proposed regulation to implement this section of the law in *the Federal Register* on March 25. It is open for public comment until May 26.

Inherent Reasonableness

The Balanced Budget Act of 1997 (BBA) made important changes in our ability to ensure that Medicare, and the taxpayers, are obtaining prices for goods and services that are competitive with what providers and suppliers charge other government agencies as well as the private sector in the market. The inherent reasonableness interim final regulation published on January 7 is an important tool to fight waste by helping us curb Medicare payments that are far higher than what other purchasers pay for the very same items.

1) Why did HCFA issue an interim final rule without opportunity for public comment?

We believe it is appropriate to publish the regulation as an interim final rule since it did not significantly change the existing methodology for application of the inherent reasonableness process that has been specified in regulations since 1986. We also believe that to delay implementation of these regulations by publishing a proposed rule would unnecessarily impede further savings to the Medicare trust funds and beneficiaries.

I want to emphasize that public comments are invited on interim final rules, and the comments we have received will be considered and discussed in the final rule.

2) The provision's legislative intent is to allow expedited payment reduction of no more than 15 percent.

Yet HCFA states it will use this streamlined payment reduction authority to cut payment by more than 15 percent via cuts of up to 15 percent in each of several years . . . Please clarify.

The legislation states that the DHHS Secretary may reduce payments by no "more than 15 percent from such payment during the preceding year. Several studies show that Medicare often pays far more than 15 percent above what others pay for the very same goods and services. This is the case with home oxygen supplies and services, where estimates of overpayment range to 40 percent and higher. Inherent reasonableness reductions are limited to 15 percent per year so that the impact of reducing payments to appropriate levels would not be too great in any given year.

3) Providers maintain this rule includes no information

... on HCFA's methods to class payments as "inherently unreasonable" so that HCFA's data and calculations cannot be independently verified Please clarify.

According to the statute, Medicare payments are inherently unreasonable when they are "grossly excessive or grossly deficient." The interim final rule which revises the current inherent reasonableness regulation retains many factors for determining whether payment amounts are grossly excessive or deficient and for setting realistic and equitable payment amounts. Criteria to be considered include: (1) whether payment amounts reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs; (2) whether payment amounts are grossly higher or lower than payments for the same category of items or services by other purchasers in the same locality; (3) whether the marketplace is not competitive; (4) whether payment amounts in a particular locality grossly exceed amounts paid other localities; (5) whether payment amounts grossly exceed acquisition or production costs; and (6) whether increases in payment amounts cannot be explained by inflation or technology.

4) Why does the rule provide only a 30 day notice prior to actual payment reductions?

The rule providing 30 days notice before the imposition of a special payment limit under this authority is not new. The 30-day time period is the same one used in the regulations on inherent reasonableness since 1986.

Competitive Bidding

The competitive bidding demonstration required by the BBA allows us to test how to apply the market-based payment method to Medicare that most other payers, public and private, use to get good quality goods and services at fair prices.

Lessons learned from this demonstration will be highly valuable once we have legislative authority to use a common sense, market-based payment method that will allow us to use taxpayer's Medicare dollars more effectively.

1) What are the final criteria that will be used to determine successful bidders?

Suppliers will be asked to submit bids including prices for individual products and information on quality, experience, capacity, and geographic service area. These bids for individual products within each category will be aggregated into a single composite bid for the supplier by weighting the bids for individual products by the ratio of allowed charges for that item to the allowed charges of all items in the product category during the most recent 12-month period. HCFA's contractor will then evaluate each supplier's composite price bid, but it is important to emphasize that we are not simply taking the lowest bidders. Suppliers also will be carefully evaluated for quality, capacity, and geographic service area. We will conduct on-site inspections of suppliers in the competitive range to verify their capacity and ability to meet quality standards.

2) What process will be used to ensure quality of care/service to beneficiaries in the demonstration sites?

Quality criteria, developed through consultation with a national technical expert panel, are being built into the bid specifications. Bidders will know in advance what quality standards they will have to meet, and will be expected to incorporate the costs of these standards in their bids. The bidders' past history of program compliance will also be part of the review. We will do a site survey of each supplier with a bid in the competitive range. We will have an ombudsman in place throughout the demonstration to investigate and resolve any complaints. Multiple violations of service criteria could lead to the suppliers' removal from the demonstration.

3) How will the financial impact of the project be evaluated/monitored?

For each demonstration site, we will select a nearby control site of about the same size, as well as compare usage and spending, before and after initiation of the competitive bidding project. We will measure the impact on suppliers by measuring changes in the volume and payments received by winning vs. non-winning bidders before and after initiation of the project.

Certificates of Medical Necessity:

Fraud, waste, and abuse have been particularly problematic with durable medical equipment, and that is why we insist the original copies of Certificates of Medical Necessity, bearing physicians' original signatures instead of faxed copies be maintained in the permanent file.

1)Accept faxed true copy

If a physician can fax a prescription for a narcotic, why doesn't HCFA accept a faxed true copy of a physician order for a wheelchair?

Unfortunately, the DHHS Inspector General, the General Accounting Office, and others agree that fraud, waste, and abuse is a major problem with durable medical equipment in Medicare, and one check against it is to make sure we are able to see the physician's original signature on Certificates of Medical Necessity. We accept faxed copies of these certificates to initiate delivery of equipment, but also require that suppliers follow up and obtain the original signed certificate for their files, because with faxed copies it is difficult to tell whether the signature is in fact valid. The DHHS Inspector General's office agrees with the need for this policy. A letter expressing the Inspector General's opinion is enclosed.

For narcotic drug prescriptions, there are several checks in place to ensure legitimacy, including strict rules and enforcement by the Drug Enforcement Administration.

2) Permit use of faxed Certificates...

In November 1997, seven national health care provider associations formally petitioned HCFA to permit use of faxed Certificates of Medical Necessity. When will HCFA respond?

On March 16, we sent a letter to Irwin Cohen, an attorney who had inquired about HCFA's policy on behalf of several provider groups. The response explained the rationale and need for HCFA's policy to prevent fraud, waste, and abuse. It also explained that while HCFA has permitted suppliers to use a faxed Certificate of Medical

Necessity to initiate delivery, the suppliers must still have the original signed Certificate of Medical Necessity on file. The Office of the Inspector General has stated that it has no objection to this requirement, providing that a time frame is established for when the supplier should have the original Certificate of Medical Necessity in its possession. A copy of our correspondence with Mr. Cohen is enclosed.

I am responding directly to Representative Greenwood with answers to his questions. In addition, on March 24, I sent a letter directly to Representative Coburn addressing his questions.

I appreciate your interest in these issues. I look forward to working with you as we continue our fight against fraud, waste, and abuse.

Sincerely,

[signature]

NANCY-ANN MIN DEPARLE

Administrator, HCFA

Enclosures



PART V

Qui Tam

The False Claims Act and Qui Tam Actions

This section will discuss the concept and how it relates to health care. **Qui tam** (kwày tæm) is an abbreviation from the Latin "*qui tam pro domino rege quam pro sic ipso in hoc parte sequitur*" meaning "who as well for the king as for himself sues in this matter."

The Law Dictionary defines a qui tam action as "an action brought by an informer, under a statute which establishes a penalty for the commission or omission of a certain act, and provides that the same shall be recoverable in a civil action, part of the penalty to go to any person who will bring such action and the remainder to the state or some other institution."

Qui tam is an ancient concept, as the Latin indicates, with its legal roots in Old England. It allows for a private citizen with knowledge of a violation of the federal False Claims Act to bring an action on behalf of the Government for a variety of practices. In the Health Care field, these include:

Billing for services not performed or required
Falsifying the nature of the services provided
Falsifying the nature of the services billed

The federal False Claims Act does not limit itself to health care, although those types of cases make up a large percentage of Qui tam actions pending. Other types of cases include:

Defense contractor fraud
Insurance company fraud
University and college fraud involving government funding
Fraud involving other government contractors or entities receiving government funding

For well over a century defense contractors and weapons manufacturers have defrauded the government. As early as the Civil War, the government was faced with fraud by defense contractors. In an effort to curtail this fraud, Congress passed the False Claims Act ("FCA") in 1863.

An important feature of the FCA was its qui tam provisions, which allowed private citizens to prosecute claims on behalf of the United States against any person who knowingly submitted a false claim to the government. Under the original FCA, the qui tam plaintiff kept one-half of the government's recovery. In essence, the FCA empowered and even encouraged ordinary citizens to act as private attorneys general. For a variety of reasons, the FCA was seldom used during the late 1800s and early 1900s. This period of relative inactivity was followed in the 1940s by problems with "parasitic lawsuits." These lawsuits were FCA claims brought on behalf of the

government but based on information already in the government's possession. In such cases the relator (the informant) was not contributing any new information but was still sharing in the recovery. Such a situation is contrary to the original purpose of encouraging citizens to bring concealed or secret information to the government which the government would most likely not uncover through its own investigations.

During the 1980s the government was again faced with the problem of widespread fraud in the defense industry. As President Reagan increased the national defense budget, over-billing and false claims became an increasingly serious problem. According to the Senate Report concerning the 1986 amendments to the FCA, in 1985, "45 of the 100 largest defense contractors, including nine of the top ten, were under investigation for multiple fraud offenses." Equally frustrating for Congress was the inability of the Department of Justice to stop this fraud. In 1985, for example, the federal government spent in excess of one trillion dollars. During that same year, estimated fraudulent claims against the government exceeded \$50 billion. In fact, the Department of Justice estimated that fraud was "draining 1 to 10 percent of the entire Federal budget." To the dismay of Congress, the Department of Justice was able to recover less than \$28 million through its civil fraud cases. Thus, the Department of Justice recovered less than one-tenth of one percent of the estimated \$50 billion in fraudulent claims against the government in 1985.

These recovery statistics, along with the growing media attention to fraud against the government, sent Congress scurrying to find better ways of prosecuting and recovering in fraud cases. One proposed solution was to revitalize the FCA. Senator Charles Grassley of Iowa, and Representative Howard Berman of California, pushed the 1986 amendments to the Act through Congress. The amendments contained provisions to encourage *qui tam* plaintiffs by increasing their share of the recovery, guaranteeing some portion of the recovery (as opposed to the possibility of sharing in the recovery under the old law), and protecting them from retaliation by the defendant/employer. Since the passage of the 1986 FCA amendments, the volume of *qui tam* litigation has grown each year, as has the recovery to the United States. The figures below illustrate the growth in the number of *qui tam* claims between fiscal years 1987 and 2014.

Total Recoveries Just Keep Getting Bigger

Total *qui tam* recoveries are now in the billions of dollars, with thousands of *qui tam* cases filed since the False Claims Act was amended in 1986. Here are figures from the US Dept. of Justice concerning *qui tam* actions involving only the US Dept of Health and Human Services.

Going back several years in Medicare overbilling cases; in February 1997, SmithKline Beecham Clinical Laboratories, Inc. agreed to pay \$325 million to settle a group of *qui tam* claims. The claims alleged that "...the company submitted false and inflated bills to Medicare, Medicaid and other federal health plans." Earlier, in 1996, Laboratory Corporation of America Holdings ("Labcorp") agreed to pay \$182 million to settle a *qui tam* action brought by four relators who alleged that Labcorp billed Medicare for unnecessary blood tests. Also in 1996, Damon Clinical Laboratories, Inc. paid \$119 million to settle similar allegations. Clearly, the revitalized FCA has improved the government's ability to recover on fraudulent claims.

Total Qui Tam Recoveries

| Fiscal Year | Total Cases | Total Settlements |
|-----------------|-------------|-------------------|
| 1987 | 3 | \$0 |
| 1988 | 5 | 355,000 |
| 1989 | 16 | 5,099,661 |
| 1990 | 11 | 903,158 |
| 1991 | 12 | 5,420,000 |
| 1992 | 15 | 2,192,478 |
| -and so on,,,,; | | |
| 2008 | 231 | 969,313,659 |
| 2009 | 279 | 1,394,619,974 |
| 2010 | 383 | 1,963,510,938 |
| 2011 | 417 | 2,270,301,404 |
| 2012 | 414 | 2,504,096,869 |
| 2013 | 504 | 2,523,689,075 |
| 2014 | 470 | 2,271,159,011 |
| 2015 | 426 | 1,472,783,885 |
| 2016 | 501 | 2,427,980,533 |

[Ed. Update: The \$2.3 billion in health care fraud recoveries in fiscal year 2014 marked four straight years the department recovered more than \$2 billion in cases involving health care fraud. Additional information on the government's efforts in this area is available at Medicare.gov/fraud.]

As noted, the SmithKline, Labcorp and Damon Clinical Laboratories cases were all settled rather than adjudicated at trial. This frequently occurs in cases relating to the medical industry, where public image is important for patient development and profitability. Medical organizations will often attempt to resolve FCA actions as quickly and quietly as possible to avoid adverse publicity. Therefore, as qui tam actions become more prevalent, particularly in the medical industry, so do issues relating to the settlement of FCA claims.

Faced with a great deal of bad publicity regarding federal budget deficits and sky-rocketing defense spending, as well as public outcries over \$500 toilet seats and coffee pots, Congress decided to take action to fight fraud against the government. The combination of bad press and an unfavorable decision in a court case (*Wisconsin v. Dean*) motivated Congress to amend the FCA a second time. The qui tam plaintiff may receive between 18 and 30% of any recovery. Congress provided for a large incentive given the huge potential losses from the variety of fraud which is committed each year.

More Health Care Fraud

The \$2.3 billion in health care fraud recoveries in fiscal year 2014 marked four straight years the department recovered more than \$2 billion in cases involving false claims against federal health care programs such as Medicare, Medicaid and TRICARE, the health care program for the military. In 2009, the U.S. Attorney General and Health and Human Services Secretary announced the creation of an interagency task force, the Health Care Fraud Prevention and Enforcement Action Team (HEAT), to increase coordination and optimize criminal and civil enforcement. This coordination yielded

historic results: from January 2009 through the end of the 2014 fiscal year, the department used the False Claims Act to recover \$14.5 billion in federal health care dollars. Most of these recoveries relate to fraud against Medicare and Medicaid. Additional information on the results of the government's efforts in this area is available at the Department of Justice website, fraud statistics overview.

The pharmaceutical industry accounted for a substantial part of the \$2.3 billion in health care fraud recoveries in fiscal year 2014. The health care company Johnson & Johnson and its subsidiaries, Janssen Pharmaceuticals and Scios (J&J), paid \$1.1 billion to resolve False Claims Act claims relating to the prescription drugs Risperdal, Invega and Natrecor. The government alleged that J&J promoted the drugs for uses not approved as safe and effective by the U.S. Food and Drug Administration (FDA). Because J&J marketed the drugs for uses not covered by federal health care programs, the company's promotion of the drugs caused physicians and other health care providers to submit hundreds of millions of dollars in alleged false claims against Medicare, Medicaid, TRICARE and other federal health care programs. The government also alleged that J&J paid kickbacks to physicians and to Omnicare Inc., the nation's largest provider of pharmaceuticals to nursing homes and long-term care facilities. In addition to the federal civil settlement, J&J paid more than \$600 million in civil claims for state Medicaid programs and \$485 million in criminal fines and forfeitures, making this \$2.2 billion global resolution of the government's claims one of the largest health care fraud settlements in U.S. history.

In a separate settlement, the department also recovered \$116 million from Omnicare. The settlement resolved allegations that Omnicare engaged in a kickback arrangement with skilled nursing facilities to induce the facilities to select Omnicare as their pharmacy provider, in violation of the Anti-Kickback Statute, which prohibits offering, paying, soliciting or receiving remuneration to induce referrals of items or services covered by Medicare, Medicaid and other federally funded programs. The statute is designed to ensure that the decisions of doctors and other professionals in prescribing drugs or recommending providers are driven by the needs of the patient and not the prospect of personal gain. Since claims for services or supplies induced by kickbacks are not eligible for reimbursement under federal health care programs, the government alleged that these claims violated the False Claims Act. In addition to recovering \$116 million in federal claims, the government recovered \$8.2 million that will go to states that jointly funded the Medicaid programs impacted by Omnicare's conduct.

Cases involving hospitals resulted in \$333 million in fiscal year 2014 settlements and judgments, with significant recoveries from two hospital chains. Community Health Systems, Inc., the nation's largest operator of acute care hospitals, paid \$98.15 million to settle allegations that it billed Medicare, Medicaid and TRICARE for inpatient services that should have been provided in a less costly outpatient or observation setting. Halifax Hospital Medical Center and Halifax Staffing Inc., hospital service providers in Florida, paid \$85 million to resolve allegations that it violated the Stark Law, which prohibits hospitals from billing Medicare for certain services when referred by physicians who have a financial relationship with the hospital.

The government also had significant recoveries for home health services provided in alleged violation of the False Claims Act. Amedisys Inc., one of the nation's largest providers of home health services, paid \$150 million to resolve allegations that it billed

Medicare for medically unnecessary services, for services to patients who were not homebound and for violations of the Anti-Kickback Statute. The government alleged that Amedisys management pressured nurses and therapists to provide care based on the financial benefits to Amedisys rather than the needs of patients.

In a trio of cases involving cardiac procedures, the government recovered \$85 million based on claims involving potentially life threatening conduct. Boston Scientific Corp., which purchased Guidant LLC and Guidant Sales LLC, and Cardiac Pacemakers Inc. in 2006, paid \$30 million to settle claims that Guidant sold defective heart devices to health care facilities that implanted them into Medicare patients. The devices were small defibrillators surgically implanted into patients' chests. When a working device detects an irregular heartbeat, it sends an electrical pulse to shock the heart back to its normal rhythm. The Guidant devices allegedly short circuited, rendering them ineffective. In the other two cases, Kentucky hospitals King's Daughters Medical Center and Saint Joseph Health System Inc. billed Medicare and Medicaid for coronary procedures that the government alleged were unnecessary. King's Daughters paid \$39 million in federal claims and \$2 million in state Medicaid claims to settle allegations that it billed for medically unnecessary coronary stents and diagnostic catheterizations, and that it had prohibited financial relationships with physicians referring patients to the hospital. St. Joseph's paid \$16 million in federal claims and \$366,000 in state Medicaid claims to settle allegations that St. Joseph Hospital in London, Kentucky, billed Medicare and Medicaid for numerous invasive cardiac procedures that were performed on patients who did not need them, including procedures involving coronary stents, pacemakers, coronary artery bypass graft surgeries and diagnostic catheterizations.

Other Fraud Recoveries and Actions

Although mortgage, housing and health care fraud dominated recoveries for fiscal year 2014, the department has aggressively pursued fraud in government procurement and other federal programs.

Significant recoveries include settlements with Hewlett-Packard Co. and The Boeing Co. Hewlett-Packard paid \$32.5 million to resolve claims involving a contract for IT products and services with the U.S. Postal Service. Boeing paid \$23 million to settle alleged false claims for labor on maintenance contracts for the C-17 Globemaster aircraft with the U.S. Air Force.

In addition, the government filed lawsuits against a number of government contractors. In a lawsuit against Kellogg, Brown & Root (KBR) and two foreign subcontractors arising from claims in connection with KBR's contract with the U.S. Army to provide wartime logistical support, the government alleged that KBR employees took kickbacks from two subcontractors in return for favorable treatment in the award and performance of numerous subcontracts for maintenance, transportation and other services in Iraq. The alleged scheme resulted in inflated prices for services and equipment that were often deficient or not provided at all. Three KBR employees previously pleaded guilty to taking kickbacks or making false statements in connection with the allegations made in the government's complaint.

Recoveries in Whistleblower Suits

Of the \$5.69 billion the government recovered in fiscal year 2014, nearly \$3 billion related to lawsuits filed under the *qui tam* provisions of the False Claims Act. During the same period, the government paid out \$435 million to the individuals who exposed fraud

and false claims by filing a *qui tam* complaint, often at great risk to their careers. The number of *qui tam* suits rose from 30 in 1987, to 300 to 400 a year from 2000 to 2009, to more than 700 for each of the last two fiscal years. The growing number of *qui tam* lawsuits filed since 2009 has led to increased recoveries, which exceeded \$2 billion for the first time in fiscal year 2011. As recoveries increased, so have whistleblower awards. From January 2009 to the end of fiscal year 2014, the government paid awards in excess of \$2.47 billion. "We acknowledge the men and women who have come forward to blow the whistle on those who would commit fraud on our government programs," said Acting Assistant Attorney General Branda. "In strengthening and protecting the False Claims Act, Congress has given us the law enforcement tools that are so essential to guarding the treasury and deterring others from exploiting and misusing taxpayer dollars. We are grateful for their continued support."

In 1986, Senator Charles Grassley and Representative Howard Berman led successful efforts in Congress to amend the False Claims Act to, among other things, encourage whistleblowers to come forward with allegations of fraud. In 2009, Senator Patrick J. Leahy, along with Senator Grassley and Representative Berman, championed the Fraud Enforcement and Recovery Act of 2009, which made additional improvements to the False Claims Act and other fraud statutes. And in 2010, the passage of the Affordable Care Act provided additional inducements and protections for whistleblowers and strengthened the provisions of the federal health care Anti-Kickback Statute. Acting Assistant Attorney General Branda also expressed her deep appreciation for the many dedicated public servants who investigated and pursued these cases – the attorneys, investigators, auditors and other agency personnel throughout the Civil Division and the U.S. Attorneys' Offices, as well as the agency Offices of Inspector General, and the many federal and state agencies that contributed to the department's recoveries this past fiscal year.

"Without the tremendous talent and dedication of the public servants who worked tirelessly to bring these matters to settlement or judgment, the nearly \$6 billion in recoveries we announce today would not have been possible," said Branda. "I commend them all for their exceptional efforts."

Proposed Law Affects Qui Tam- a Hearing on this Issue

LEGISLATION THAT WOULD AFFECT THE FALSE CLAIMS ACT LOSES SUPPORT AFTER DOJ AND HHS ISSUE GUIDELINES

At the urging of the American Hospital Association, legislation was introduced in March of 1998 to amend the False Claims Act. The bills would have created a separate liability standard for health care providers submitting false claims. Specifically, the legislation would have limited FCA actions to only those where damages are a "material amount." That could mean up to 10% of the provider's total Medicare billings. The legislation would also exempt claims made "in reliance on official guidance" and by providers who are "in substantial compliance with a model compliance plan." Additionally, the bills would elevate the standard of proof from "preponderance of the evidence" to "clear and convincing evidence." Finally, the provisions would be applied retroactively to preclude liability for false claims already submitted.

Broad-Based Coalition of Groups Opposed to Changes

After the legislation was introduced, groups opposing it appeared. Among other problems, the groups noted that the legislation would create "free fraud zones" and severely weaken the Government's most effective tool against fraud. Moreover, because of the retroactivity provision, the groups warned that the legislation could impede ongoing fraud investigations, including the pending investigation of Columbia/HCA. Calling for a strong False Claims Act, the groups further cited the recent HCFA audit which showed over \$20 billion in "improper payments" to Medicare providers last year. On June 4, the Department of Justice released a letter communicating the official Administration position on H.R. 3523/S. 2007. The Department said that it "strongly opposes" the bill because it would "fundamentally undermine our law enforcement efforts to protect the integrity of the Medicare Trust Funds." Describing the legislation as providing "preferential treatment to the health care industry," the Attorney General recommended that the President veto H.R. 3523/S. 2007 should the legislation be passed by Congress.

April 28, 1998 Hearing

On April 28, 1998, hearings on health care initiatives pursued under the False Claims Act were held before the House Subcommittee on Immigration and Claims, Committee on the Judiciary. The American Hospital Association and hospital officials testified in favor of legislative change to the Qui Tam arrangement. Other political group's testimony was against the proposed changes.

STATEMENT OF LEWIS MORRIS, ASSISTANT INSPECTOR GENERAL LEGAL AFFAIRS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, and members of the Committee. I am Lewis Morris, Assistant Inspector General for Legal Affairs in the Office of Inspector General (OIG), U.S. Department of Health and Human Services (HHS). I appreciate the opportunity to testify before you today on health care initiatives pursued under the False Claims Act. In particular, I wish to voice our very serious concerns about recent efforts to dilute the effectiveness of the Act, as the Act applies to the health care industry in this country.

There is before this Committee a proposal by the American Hospital Association (AHA) that would raise unprecedented barriers to the Government's ability to pursue those who knowingly or recklessly take advantage of our taxpayer-supported health care programs. We urge the Congress to weigh carefully the impact of this AHA proposal on worthy law enforcement efforts, and to reject its overly lenient standards for establishing health care fraud.

In my testimony, I will provide an overview of the extent of fraud and other systemic vulnerabilities, the available enforcement tools, the troubling ramifications of the AHA proposal, our national projects, and our extensive efforts to work proactively with industry to develop appropriate fraud prevention measures.

1. Extent of Fraud and Other Improper Practices

FYs 1996 and 1997 Financial Statement Audits of HCFA Billing errors and billing fraud are costing Medicare billions of dollars. Just last Friday, on April 24, 1998, the OIG issued its 1997 Financial Statement Audit of the Health Care Financing Administration

(HCFA). We estimate that the dollar value of improper Medicare fee-for-service benefit payments made during FY 1997 totaled approximately \$20.3 billion nationwide. This \$20.3 billion represents about 11 percent of the \$177.4 billion in fee-for-services payments made by HCFA in FY 1997. The improper payments for hospital inpatient and outpatient services in FY 1997 was estimated to be \$6 billion. These numbers compare with our estimates that approximately \$23 billion in Medicare fee-for service payments in FY 1996 were improper, with improper inpatient and outpatient services payments estimated at \$8 billion.

While we do not know what portion of these amounts were attributable to fraud, this continuing error rate is unacceptably high for Medicare generally, and for hospitals in particular. We have encountered enough examples of reckless billing practices to be very concerned about the extent of fraud. In fact, the above audit figures may not reflect the magnitude of Medicare fraud. Sophisticated fraud schemes fabricate the necessary medical documentation in an effort to thwart detection. Our recent audits of HCFA might not uncover such a scheme.

Simply put, Medicare is highly vulnerable to fraud and other improper billing practices. One problem is the program's sheer size. Today, Medicare outlays exceed \$200 billion annually; it has 38 million beneficiaries, and its contractors process and pay well over 800 million claims per year. Since only about 9% of Medicare claims are reviewed, the program is highly dependent on the care and honesty with which providers prepare and submit claims. Providers have a duty to prepare true and accurate claims for their goods and services.

Hospitals

I would now like to share just a few examples of fraud uncovered by the Government in the hospital industry;

In 1995, a component of a large east coast university health system agreed to pay \$30 million to the U.S. Government to settle allegations that the institution submitted false Medicare bills for faculty physician services. The institution's own internal memos showed it knew that for a physician to bill for a service performed by a resident, the physician had to be physically present, "at the elbow" of the resident. However, the institution encouraged its physicians to bill for services performed by others. The second questionable practice was billing by faculty physicians for inpatient services at the highest levels of the 5-tier coding system for hospital visits, without reference to the services actually performed. In fact, the institution printed forms for physician billing which left off the two lowest-reimbursed codes altogether.

In 1997, two east coast billing consultants settled charges that they enlisted more than 100 hospitals in schemes to aggressively and inappropriately manipulate Medicare's billing rules to increase payments. Some hospitals did the right thing, and told the consultants that their advice promoted fraud and would not be followed. Unfortunately, many hospitals used the consultants to make a quick buck at the Medicare program's expense. As part of the settlement with the U.S. Attorney's Office, the consultants have agreed to cooperate in the Government's ongoing investigation of these hospitals.

In 1997, a Midwest medical center agreed to pay \$17.5 million arising out of allegations that it paid two physicians over \$1 million to refer an estimated \$42 million in Medicare business to the hospital. The hospital designed sham "consulting agreements" with the physicians and paid them over an 11-year period in exchange for patient referrals. The

doctors did not perform the services specified in the agreements and were paid far more than market value for those they did perform.

In all of these hospital cases, the False Claims Act was an essential component of the Government's enforcement effort. The AHA proposal to amend the False Claims Act would adversely affect enforcement efforts with respect to all health care providers, not just hospitals. Here's a sample of what we are uncovering in other health care industries:

- **Laboratories**

During FY 1997, OIG concluded "Labscam," a multi-year interagency initiative targeted at abusive marketing and billing practices by the nation's largest independent clinical laboratories. We found a number of improper activities, including unbundling clinical laboratory tests, billing for tests not performed, inserting false diagnosis codes to obtain reimbursement, double billing for laboratory tests for patients with end stage renal disease, payment of kickbacks, and billing for calculations which were both unordered and medically unnecessary. The Federal Government's case against the abusive laboratories, all told, resulted in three corporate criminal convictions, and will ultimately produce recoveries of more than \$800 million.

- **Home Health**

First American Health Care of Georgia, Inc. was the largest privately held home health care provider in the country. When our investigation began, the company was known as ABC Home Health, and Jack and Margie Mills were the majority shareholders and chief officers of the company and its subsidiaries. Offenses included shifting unallowable costs to Medicare. The company and its owners claimed items and services that benefited the owners personally as reasonable and necessary "general and administrative" expenses related to the care of Medicare patients. These fraudulent claims included golf course memberships, greens fees, a family vacation, and a BMW for a son in college. After extensive investigation and audits by the Office of Inspector General, the Mills and the parent company were convicted in 1996 of several Medicare-related criminal offenses and received significant prison time. In a related settlement, \$255 million was returned to the United States.

On a smaller scale, the co-owner of a Washington, D.C. home health agency billed for 1,450 skilled nursing visits for which there was no evidence that the visits were made. It also billed for home nurse visits when patients were actually hospitalized. The co-owner was sentenced to 27 months in prison and ordered to pay full restitution of \$100,000 defrauded from the Medicare and Medicaid programs.

- **Medical Equipment and Supplies**

One of the highest-reimbursed Medicare suppliers of incontinence care products, Ben Carroll, agreed to plead guilty to conspiracy to defraud Medicare of more than \$70 million. He had actually collected \$45 million. He distributed adult diapers (which are not covered by Medicare) but billed Medicare for female urinary collection pouches. He agreed to forfeit \$32 million in seized bank accounts, paid \$2.5 million in restitution, and was sentenced to 10 years imprisonment.

2. Critical Enforcement Tools Provided by Congress

The above examples hint at the breadth of the improper practices plaguing Medicare and other federally funded health care programs. To stem the tide of abuses and to

protect Medicare's beneficiaries, we have adopted an attitude of "zero tolerance" of Medicare fraud and abuse. And we are pleased that the American Hospital Association and many other groups have embraced the "zero tolerance" goal. To achieve this goal, the Government relies on a number of enforcement options- criminal, civil, and administrative, as well as educational outreach efforts. Chief among the enforcement tools has been the False Claims Act.

Congress deserves great credit for its amendments to the False Claims Act in 1986, amendments that have improved the Government's ability to recover false or fraudulent payments. Now, the False Claims Act imposes treble damages liability and civil penalties of \$5,000 - \$10,000 per claim on any person who knowingly presents, or causes to be presented, a false or fraudulent claim for approval to the U.S.

Government. See 31 U.S.C. sec. 3729.

The Act is the primary means of recovering damages for losses to the Medicare Trust Fund (and to the U.S. Treasury as a whole). It is also the primary means of recovering fraudulently claimed dollars from health care providers, including hospitals. To prove liability, the Government must show actual knowledge of falsity, reckless disregard for truth or falsity, or deliberate ignorance of truth or falsity. "Deliberate ignorance" reaches those who consciously ignore or fail to inquire about readily discoverable facts that would alert them that a given claim is false.

It is absolutely critical to note that billing errors due to simple negligence, mistakes, or inadvertence are actionable under the False Claims Act. The government must prove at a minimum a "deliberate ignorance" or a "reckless disregard" of the truth or falsity of the claims submitted by the provider.

In our experience, the penalty provisions of the False Claims Act are also a crucial deterrent to repeat offenders. If a provider or supplier gets caught actually bilking the system, i.e., submitting claims recklessly, and only has to pay the money back, there is precious little incentive for the wrongdoer to stop.

The qui tam provisions of the False Claims Act, also amended in 1986, have provided the incentive for whistle blowers to overcome the substantial detriment and obstacles to speaking out. Most of the time, a whistle blower is a health care employee with inside knowledge of wrongdoing. When he/she blows the whistle, he/she invariably becomes an outcast in the industry. However, the qui tam provisions allow such whistle blowers to act as private attorneys general and bring suit under the False Claims Act seeking recoveries against defrauders of government programs. The Department of Justice then determines whether or not to intervene in the case; the case may proceed without DOJ. In either case, the whistle blower, or "relator," may share in any later recoveries. In just the hospital industry alone, from January 1, 1995 to April 17, 1998, OIG's figures show that 199 qui tams were filed against hospitals. The law is working as intended. Whistle blowers are stepping forward, and billions in false claims are being recovered as a result. In the last ten years, qui tam cases in which the government has intervened have produced approximately \$1.8 billion in recoveries. About half of these recoveries were in health care cases.

The AHA proposal will adversely impact the fight against health care fraud and abuse. While the AHA proposal does not amend the qui tam provisions themselves, it would make the underlying substantive cause of action quite onerous to pursue. Thus, the qui tam provisions will effectively be gutted. The crucial information provided by whistle blowers will be lost in most cases because the insiders will not come forward to the Government.

Health Care Fraud and Abuse Control Program Mandated by the Health Insurance Portability and Accountability Act (HIPAA)

Congress has repeatedly recognized the magnitude of health care fraud, and has provided other crucial fraud fighting tools. In 1996, Congress and the President gave law enforcement a major boost through the Fraud and Abuse Control Program, authorized in the Health Insurance Portability and Accountability Act of 1996. The program is designed to provide a framework and resources to coordinate Federal, State, and local law enforcement efforts. It mandates a comprehensive program of investigations, audits, and evaluations of health care delivery; authorizes new criminal, civil, and administrative remedies; requires guidance to the health care industry about potentially fraudulent health care practices; and establishes a national data bank to receive and report final adverse actions imposed against health care providers. The Act also provides an innovative mechanism to fund these new anti-fraud efforts, thereby assuring that needed resources are always available for the effort.

The recent report detailing the substantial recoveries to the Medicare Trust Fund brought about by HIPAA demonstrates that the Congress invested wisely in the effort to control health care fraud and abuse. Indeed, in January, 1998, HHS and DOJ jointly issued the first annual report of the Health Care Fraud and Abuse Control Program. The report provides some helpful measures of recent progress made in the effort to control health care fraud and abuse. During fiscal year 1997:

- \$1.087 billion was collected in criminal fines, civil judgments and settlements, and administrative impositions.
- \$968 million was actually transferred to or restored to the Medicare Trust Fund , and \$31 million was recovered as the federal share of Medicaid restitution.
- More than 2,700 individuals and entities were excluded from federally sponsored health care programs, a 93% increase over 1996.
- Federal prosecutors opened 4,010 civil health care matters, an increase of 61 percent over 1996.

At the same time, it is important to keep these results in perspective. Hospitals paid approximately \$73.2 million last year to settle potential False Claims Act liabilities with the government, while they received over \$100 billion in Medicare payments.

The bottom line is that the problem of health care fraud is real and it is massive in scope. The AHA proposal would hamstring the Government's use of the most important tool we have in stemming the tide. I will now briefly share some specific reasons why this would occur.

3. The American Hospital Association's Proposal

Individual Provisions

The AHA proposal would erect serious obstacles to pursuing Federal health care fraud. Curiously, these obstacles would not be imposed on any other defrauders of federal programs. But under the AHA's proposal, regardless of what some advocates state, members of the health care industry would enjoy from the False Claims Act in many situations.

I. Material Amount Required in Order to Be Actionable

Under the AHA proposal, for a false claim to be actionable where submitted to a "federally funded health care program" (e.g., Medicare, Medicaid, the Children's Health Insurance Program), the Government's damages must be for a "material amount." That term would more specifically be defined in regulations to be promulgated by the Secretaries of Health and Human Services and Defense. Because the AHA seeks to have its proposal made retroactive in effect, current enforcement efforts would grind to a

halt until a regulatory definition of "materiality" successfully navigates the protracted rule making procedures. And defining when the Government's fraud losses are "material" would defy a simple answer.

The AHA proposal mandates that the American Institute of Certified Public Accountants' (AICPA) definition of materiality be used in the joint HHS and DOD regulations. AICPA defines materiality as "the magnitude of an omission or misstatement of accounting information that, in the light of the surrounding circumstances, makes it probable that the judgment of a reasonable person relying on the information would have been changed or influenced by the omission or misstatement." This is explicitly and necessarily a subjective standard. AICPA itself recognizes that "an illegal payment of an otherwise immaterial amount could be material if there is a reasonable possibility that it could lead to a material contingent liability or a material loss of revenue."

While the AHA proposal seems to require that the Secretary quantify a specific proportion of an entities' claims that must be fraudulent before being deemed "material," AICPA makes plain that what is material is very much context dependent, and requires the consideration of any number of quantitative and qualitative factors. While useful for accounting purposes, this is not a workable standard for an enforcement statute of general applicability.

Specifically, it would be quite inappropriate to create some set percentage or dollar threshold below which fraud would go unpunished. For example, the AHA has suggested a threshold of \$100,000 of false claims in any claim category before the False Claims Act could apply. AICPA suggests, from an accounting perspective, that materiality may range from 5% to 10%. Such proposals would result in large "free for fraud" zones. If you multiply the number of providers by the number of potential categories, many billions of dollars could be fraudulently claimed with no remedy under the False Claims Act. While most everyone voices support for "zero tolerance" for fraud, this AHA proposal amounts to a safe harbor for fraud, as long as the loss to the Medicare program is not too big in any one of a provider's categories of claims.

The AHA proposal mandates other prerequisites to finding "materiality." Only Medicare claims can be aggregated with other Medicare claims when demonstrating that a claimant has surpassed the "material" threshold, and then, only if the claims are made in the same calendar year. Consequently, the same claimant may well be defrauding Medicaid, but those false claims must be counted separately. Claimants would be free to cheat so long as they are savvy enough to consistently steal only a "non-material" amount from each program, each year.

Furthermore, under the AHA proposal, improper claims cannot be aggregated in order to establish materiality unless they can be shown to have been part of a "pattern" of "related acts or omissions." These barriers further reduce the remote possibility that the government could demonstrate materiality with respect to false claims by any but the smallest and most corrupt Medicare providers.

What is "material" at a Fortune 500 corporation invariably will not be so for a small "mom and pop" health care company. Many corporate financial statements, particularly those of massive health care conglomerates, might not consider even a \$1 million contingent liability as material relative to total assets. The AHA proposal may well give such a \$1 million false claim a "free pass," because if the corporation bills Medicare \$100 million each calendar year, \$1 million may not be deemed "material."

Consequently, enforcement will likely become regressive, in that smaller health care entities will be the primary target of False Claims Act enforcement.

II. Standard of Proof Ratcheted Up

The AHA proposal raises the standard of proof for all false claims to federally funded health care programs, even claims that manage to satisfy the onerous "materiality" requirements. "Clear and convincing evidence" (much closer to a criminal standard) would be required, rather than a preponderance" standard (the standard in civil cases). This relaxed standard will invite members of the health care industry to be less vigilant in avoiding abusive behavior.

III. Model Compliance Plans - A "Substantial Compliance" Safe Harbor

The AHA proposal seeks to immunize claimants who are in "substantial compliance" with a model compliance plan issued by the HHS Secretary in conjunction with the DOD Secretary. This vague term ("substantial compliance") will require definition, presumably by regulation. We are greatly concerned as to how it will be determined what constitutes "substantial compliance."

The AHA proposal, by its own language, does not mandate that HHS/DOD issue compliance plans, nor are they mandated anywhere else. HHS has never issued such plans in conjunction with DOD. More importantly, the "model compliance" issued to date by HHS has been non-binding "guidance," not the text of actual compliance plans. This guidance approach, requested by trade groups, including AHA, allows actual compliance plans to be flexible and to be tailored to the needs and capabilities of the individual provider. It should be noted that the OIG and (heretofore) the health care industry agree that there can be no "one size fits all" compliance scheme.

The AHA proposal thus creates yet another anomaly: under the U.S. Sentencing Commission guidelines, an effective compliance plan warrants just a downward adjustment with respect to fines imposed upon a corporate defendant for its criminal conduct. By contrast, the AHA proposal would grant civil immunity to health care defrauders with a compliance plan. Ironically, conduct which enjoys civil immunity could still be the subject of a criminal prosecution.

IV. Safe Harbor for Reliance on "Agency" Advice

The AHA proposal also seeks to immunize claimants who have relied on erroneous information from a "Federal agency," or "an agent thereof." First, we always take guidance of carriers, intermediaries and other official pronouncements into consideration in our cases. It is only fair that we do so. However, the AHA proposal goes much further. The AHA proposal invites claimants to "shop" carrier and intermediary personnel, and encourages "gaming" of the system. Under the AHA proposal, the erroneous guidance does not even have to be in writing for a fraudster to benefit from this immunity provision.

There is a longstanding general principle that "the United States is neither bound nor estopped by acts of its officers or agents in entering into an arrangement or agreement to do or cause to be done what the law does not sanction or permit." *Utah Power & Light Co. v. United States*, 243 U.S. 389, 409 (1917). See also *Federal Crop Insurance Corp. v. Merrill*, 332 U.S. 380 (1947) (court held that the government was not bound by the unauthorized representations of its agents in advising a farmer that his crop was insured when, under regulation, over 80% was not). Although more recent case law and the decisions of the Comptroller General have softened this rule of law, a person relying on erroneous advice must show his/her reliance was reasonable under the circumstances.

Where the issue of contractor guidance arises, we consider whether the agency or contractor guidance was in fact inaccurate, whether the provider in fact relied upon it and, indeed, whether that reliance was reasonable in light of other available information. The AHA's suggested "safe harbor," however, would confer immunity even when the

provider knew that the person providing the guidance was acting outside of his or her authority or was providing misinformation.

Again, with respect to HCFA and HCFA contractor guidance, it must be emphasized that law enforcement most certainly takes into consideration whether there was reasonably clear guidance in place before a case is pursued. This is a key factor in evaluating whether behavior was egregious, or a simple mistake based on good faith reliance on erroneous advice.

Although we believe the AHA proposal is not the answer to the concerns that have brought us here today, we wish to address the objections by the industry to the concept of national enforcement projects. Specifically, I will discuss in detail the "DRG 72 Hour Window" project, which is the subject of particular industry concern.

4. National Projects

When the federal law enforcement community detects repeated and widespread violations of the same or related Medicare rules, we may undertake nationwide projects targeting that abuse. National projects also allow us to pursue abuses that are not large cases individually, yet, collectively, cause significant drains on the Medicare Trust Fund. While these are national projects focused on pervasive abuse, it is also important to keep in mind that each case is evaluated and pursued on its own merits.

The industry proponents of the relaxing of False Claims Act standards have been critical of these OIG and DOJ-coordinated national enforcement efforts. We feel that it is important for us to dispel misconceptions about these initiatives. As an example, the first national project affecting all Medicare hospitals was the "DRG 72 Hour Window" project. The rule underlying this project is simple. Hospitals which are paid by Medicare under the Prospective Payment System ("PPS") receive a set amount for hospital admissions for particular types of illnesses ("Diagnostic Related Groups" or "DRGs"). The Medicare regulations require that non-physician outpatient services rendered in connection with such hospital admissions (and within a three day "window" of such admissions) not be billed separately to Medicare. Rather, such services are included in the pre-established fee paid to the hospital for the admission itself.

Between 1987 and 1992, the OIG performed four nationwide audits of the Prospective Payment System (PPS) hospitals' billing of non-physician outpatient services. Each audit revealed widespread violation of the "DRG 72 Hour Window" rule. The first OIG audit covered the period between October 1983 and January 1986. OIG determined that approximately \$28 million was improperly paid to hospitals in violation of the rule during that time frame. The OIG supplied HCFA with computer listings of the claims paid improperly. HCFA, through its contractors, then pursued repayment, and put the hospitals on formal notice of their noncompliance.

The second OIG audit covered payments made to hospitals between February 1986 and November 1987. This time, approximately \$40 million in improper payments were identified. Once again, OIG asked HCFA to recoup the payments and put the hospitals on notice. Yet again, HCFA recovered the improper payments, and put the hospitals on notice of their improper billing practices.

When OIG revisited the issue a third time, it was found that approximately \$38.5 million in improper payments for the period December 1987 to October 1990. HCFA again expended the considerable resources necessary to recover the overpayments.

After each of the first three audits, HCFA instructed the Medicare fiscal intermediaries to recover the overpayments and further educate the hospitals how to conform to the rule. Each time, funds were recouped and notices issued. Unfortunately, hospitals'

performance overall did not improve despite these repeated, explicit efforts by HCFA and its contractors.

In 1993, the fourth OIG audit identified approximately another \$8.6 million in improper billings from November 1990 to December 1991. By this point, the HCFA contractors had been catching more of the claims before they were paid. All told, the first four audits identified approximately \$115.1 million in Medicare overpayments to hospitals caused by the improper billings. The OIG presented the results to the U.S. Attorney for the Middle District of Pennsylvania to devise a plan to recover the continuing overpayments, with penalties, from hospitals in Pennsylvania. Based upon early results, the U.S. Attorney for the Middle District of Pennsylvania then developed a national plan to replicate the Pennsylvania experience across the nation.

In 1996, OIG audited this issue a fifth time, identifying an additional \$27 million in potential improper payments for the period January 1992 through December 1994. Incredibly, even after all of the previous public OIG audit reports and HCFA's repeated efforts to remind hospitals of the requirements, OIG's fifth audit revealed that with respect to the hospitals' claims processing systems, the necessary edits at hospitals were not sufficient, or were nonexistent. All of this left the question: What would it take to get hospitals to comply with the "DRG 72 Hour Window" rule?

The first four OIG audits revealed tens of thousands of individual small dollar overpayments by some 4,660 hospitals nationwide. Certainly, a prevalent pattern of abuse had been identified. At the same time, the individual overpayments were low (generally less than \$100 each), and the total number of improper claims submitted by individual hospitals was relatively small. The average overpayment for the entire five year period was only about \$10,000 per hospital, though some overpayments reached \$1 million. Approximately \$58 million has been recovered to date as a result of the national project efforts. In short, repeated audits and resulting recoveries of simple overpayments (with interest) and repeated notice to the industry proved wholly ineffective in stemming the abuse. Moreover, interest is normally only charged from the date an overpayment is identified, yet another windfall for the hospitals.

Innocent mistakes? Perhaps initially. But at some point, repeated failure to abide by explicit notice becomes, at a minimum, reckless behavior. We had every reason to believe that without this remedy, false claims would continue. And the Medicare program could not depend on the OIG to repeatedly audit compliance. Yet, without the continued audits, the program and taxpayers would suffer annual improper losses in the millions of dollars due to this abuse.

This recklessness has tangible and significant cost to society. The OIG and HCFA resources necessary to identify and recover these improper payments is not insignificant. And Medicare beneficiaries are injured even more directly. Many of the services billed by hospitals in violation of the "DRG 72 Hour Window" rule are subject to a 20% coinsurance, or "co-payment." Consequently, senior citizens on fixed incomes unnecessarily have paid millions to hospitals for charges which should have been included in the inpatient payment.

Even after involving the Department of Justice and the False Claims Act, we have approached this problem judiciously. A great many hospitals which violated the billing requirement were placed in what was called "Tier zero;" the False Claims Act would not be applied to these hospitals. Rather, they have or will have the opportunity to simply pay the money back with interest.

The remaining hospitals identified in the national project were divided into three tiers: Tiers 1, 2, and 3. This ranking was based primarily on a ratio of the number of false claims submitted in relation to the hospital's bed size. Hospitals with 10 or fewer false

claims were grouped into Tier 1. In settling their liability under the False Claims Act, the Tier 1 hospitals are treated just like the zero tier hospitals--they merely have to return the money with interest.

It stands to reason that the number of false claims should be considered in relation to a hospital's size, as reflected by its number of beds. Consequently, Tier 1 includes those hospitals with the lowest false claims to bed size ratio, while Tier 3 includes those hospitals with the highest ratio (and thus the most flagrant violations). False Claims Act penalties were proposed based on the severity of the hospital's conduct, beginning with Tier 2.

With the active participation of the AHA early in the national initiative, the Department of Justice and OIG developed a model settlement mechanism that included repayment with interest, penalties where appropriate, and two other important features. The first requires the hospital to conduct a review of patient accounts and records to identify instances where the Medicare beneficiaries (or the Medicaid program if the person was dually eligible for both Medicare and Medicaid) paid the hospitals for deductibles or coinsurance. Within 90 days of settlement, the hospital would agree to refund to the beneficiary, when feasible, the amount identified. A second provision of the settlement requires the hospital to establish both computerized and manual controls to prevent future billing for outpatient services included in the outpatient payment under PPS. Some statistics: It is my understanding that approximately 3,000 hospitals to date have received letters from DOJ. Some 1,700 of these have had to pay no penalty whatsoever. Approximately 500 of these 1,700 hospitals have been grouped in the zero tier, and approximately 1,200 have been grouped in the first tier. As for the flagrant, or Tier 3 cases, I would like to share a few examples.

A 560-bed east coast hospital paid \$976,035 to settle allegations that it had made 346 erroneous claims as determined by the fourth OIG audit, and 1,056 improper claims as determined by the fifth OIG audit. A 502-bed hospital in the southeast paid \$836,852 to settle allegations that it improperly made 238 claims during the fourth OIG audit period, and 1,200 improper claims during the fifth OIG audit period.

The national "DRG 72 Hour Window" project shows a reasonable approach to a situation where hospitals generally refused to recognize their collective responsibility to bill Medicare correctly. Enforcement action became necessary with respect to significant violators; the rest paid only overpayments and interest. However, OIG is not relying only on enforcement; we are seeking to engage hospitals at the front end -- to prevent their getting in trouble in the first place.

5. Compliance: The OIG's Commitment to Assisting the Health Care Industry
June Gibbs Brown, the Inspector General at HHS, is personally committed to efforts beyond just enforcing past violations and punishing wrongdoers. Under her leadership, OIG has also engaged in numerous proactive outreach efforts designed to help the industry comply at the front end, by identifying and preventing health care fraud and abuse generally. Indeed, hospitals in particular have reacted quite positively to the Inspector General's initiatives.

These outreach efforts are even made available through the Internet, to anyone who wishes to review them. For the record, the OIG Website may be found at www.hhs.gov/progorg/oig. Some of these public outreach and prevention efforts include:

The February 1998 "Office of Inspector General's Compliance Program Guidance for Hospitals." This document presents basic procedural and structural guidance for developing a hospital compliance program that will avoid false or improper claims. Hospitals owe a duty reasonably to ensure that the claims they submit to Medicare are

true and accurate. This guidance is intended to assist hospitals and their agents and subproviders to fulfill that duty. It suggests that hospitals develop effective internal controls that promote adherence to applicable federal and state law, and the program requirements of federal, state and private health plans. Fundamentally, compliance guidelines are intended to foster a culture within an organization that promotes the prevention, detection, and resolution of conduct that does not conform with Federal and State law, program requirements, or the provider's ethical and business policies. This is a critical prevention mechanism that is rapidly gaining acceptance in the health care industry. Indeed, the hospital guidance was developed with substantial input from the American Hospital Association, the American Medical Association and other industry groups. We are currently developing guides for home health providers, billing services, health maintenance organizations, and durable medical equipment suppliers.

The OIG Advisory Opinion Process-

Mandated by the Health Insurance Portability and Accountability Act, OIG issues advisory opinions to requesters on whether certain conduct, including certain business arrangements, constitutes a violation of applicable law, including, in particular, the anti-kickback statute. (The OIG advisory opinion regulations may be found at 42 CFR part 1008). Twelve such opinions have been issued to date.

Special Fraud Alerts-

While advisory opinions offer one-on-one guidance, OIG Special Fraud Alerts sweep more broadly, by seeking to identify practices in particular segments of the health care industry that are particularly vulnerable to abuse. These alerts are published in the Federal Register, posted on the Internet, and are available upon request to any interested party. As just one example, in March 1998, OIG issued a special fraud alert concerning fraud and abuse in nursing home arrangements with hospices.

OIG Workplan-

Our annual work plan is available on the Internet, so interested parties can identify areas of particular OIG interest and emphasis.

These and other efforts demonstrate our real commitment to assist providers in complying with Medicare's requirements, and avoiding the submission of improper claims. Providers owe a duty to Medicare reasonably to ensure that the claims they submit are true and accurate. We suggest that careful compliance efforts are necessary to discharge this duty. These efforts will prove cost effective for the providers in avoiding liability. Regardless, we must not forget that the lax compliance efforts of the past have been grossly damaging to the solvency of the Medicare Trust Fund .

With the above proactive examples, we have attempted to demonstrate that law enforcement is not, as suggested, looking to prosecute providers for innocent errors . On the contrary, we are engaged in an extensive, good faith effort to work with the industry to prevent potential liability for fraud and improper billing before it even occurs.

Conclusion

For the reasons explained, the Office of Inspector General strongly opposes the AHA proposal.

The False Claims Act is an invaluable tool in the Government's continuing effort to control health care fraud and abuse. In an era when the long-term solvency of Medicare is in doubt, and when our audits reveal huge losses due to improper payments, and when taxpayers, the Congress, and the Administration are rightfully demanding a more concerted law enforcement effort, it would not be wise to weaken the protections afforded by the False Claims Act.

Testimony of Robert A. Berenson, M.D., Director, Center for Health Plans and Providers

1998/04/28; HCFA Testimony; The False Claims Act

STATEMENT OF ROBERT A. BERENSON, M.D. DIRECTOR, CENTER FOR HEALTH PLANS & PROVIDERS

HEALTH CARE FINANCING ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Chairman Smith and Members of the Subcommittee, thank you for convening this hearing today to discuss hospital initiatives pursued under the False Claims Act. The False Claims Act is an important tool for our law enforcement partners to pursue fraud and abuse in the Medicare program.

Fighting fraud and abuse is one of our highest priorities. Letting providers who intentionally submit improper bills merely pay back the money turns the Medicare Trust Funds into a no interest loan program. That is something we simply cannot afford to tolerate. In too many instances, when providers found to be billing improperly were merely made to pay back the money, they went on to continue the very same improper billing practices and waited until being caught again to pay back the money. We need the penalties under the False Claims Act if we are to put an end to these deliberate improper billing practices.

The Health Care Financing Administration administers the Medicare program and, in partnership with the State, the Medicaid and Children's Health Insurance programs. The concerns raised today relate to Medicare payment for hospital services. As you know, the Medicare program provides health insurance to almost thirty-nine million aged and disabled Americans. More than 6,000 hospitals participate in the Medicare program. These hospitals provide acute inpatient care, long term, rehabilitative, and psychiatric care, as well as outpatient services to Medicare beneficiaries nationwide.

The Health Care Financing Administration maintains a commitment to working with providers to ensure that the Medicare program rules are clear. It is the provider's obligation to know these rules and to appropriately bill the Medicare program.

MEDICARE IMPROPER PAYMENT

Medicare payments for hospital services are estimated to total almost \$100 billion (including acute care hospital, pps-exempt hospital, and outpatient hospital) in Federal Fiscal Year 1998. An essential part of running this public program is ensuring that providers bill properly. Although our providers bill appropriately most of the time, there is still an unacceptable error rate.

The Fiscal Year (FY) 1997 Chief Financial Officers (CFO) audit by the Department of Health and Human Services Office of the Inspector General (OIG) estimated that net Medicare improper payments totaled \$20 billion or 11 percent of total Medicare fee-for-service benefit payments. Of the \$20 billion in improper payments, about \$6.5 billion, or 32 percent was to hospitals, including \$4 billion in acute hospital inpatient payments, \$2 billion in outpatient payments and \$4 billion in payments to long term care, rehabilitation, psychiatric and children's hospitals.

It is important to stress that we cannot determine what portion of the improper payments identified in the audit were due to fraud and abuse. It also is important to stress that Medicare contractors paid claims correctly 98 percent of the time based on information

provided on the claim. The true error rate was found only when auditors and medical experts obtained medical records from providers and discovered that the documentation did not support the claims.

The largest factor in improper payments to hospitals is claims for services that are not medically necessary. Almost fifty percent of improper hospital claims were identified by medical professionals who found that the documentation provided did not show that the service was medically necessary. These cases include some obvious abuses such as a hospital admitting a patient five years after a stroke to provide medication and physical therapy thirty-seven days.

But obvious cases are just the tip of the iceberg. We have no tolerance for fraud which is why we are developing, in conjunction with our Peer Review Organizations, pilot programs to test ways to ensure the medical necessity of inpatient hospital claims. The projects will focus on identifying unnecessary readmissions, and the necessity of billings for specific cardiac procedures. HCFA will continue its efforts to aggressively implement corrective actions to address improper payments to Medicare providers.

THE MEDICARE PROGRAM

The Medicare program has two parts, Part A and Part B. Part A of Medicare provides coverage for inpatient hospital, skilled nursing facility, hospice and some home health care. Part B provides coverage for several types of health services including physician services, outpatient hospital services, laboratory services and durable medical equipment. The Health Care Financing Administration develops policies related to the Medicare program but contracts with some seventy different insurers, referred to as "contractors," to administer Medicare, including claims processing, audit functions, and provider education.

Medicare pays for most inpatient hospital care through its prospective payment system (PPS), which pays hospitals a predetermined amount for each Medicare discharge based on the patient's diagnosis. Medicare pays hospital outpatient departments in a variety of ways depending on the service. Generally, outpatient department services are paid for based on a pre-determined fee schedule or on the lower of the hospital's costs or charges.

MEDICARE POLICY DEVELOPMENT

The Health Care Financing Administration issues policy through regulations, program memorandum to our contractors, and manual issuances to the contractors and to the providers. The Administrative Procedures Act provides direction, in most cases, on when a policy should be implemented via regulation. In addition to this formal policy guidance, HCFA consults with associations and providers on an ongoing basis to explain new legislation and regulations as well as respond to questions on existing rules.

Regulation

The Health Care Financing Administration consults with provider associations and other interested parties in developing regulations. HCFA usually starts by publishing a proposed regulation in the Federal Register with, generally, a sixty day period for public comment. HCFA considers public comments and evaluates the policy recommendations included in the public comments for inclusion in the final rule. The final rule is generally effective sixty days after publication.

Program Memorandum

The Health Care Financing Administration sends program memoranda to contractors to inform them of changes in policy or to clarify existing policy. Our contractors then communicate these policy changes or clarifications to providers. In most cases, HCFA will also send the contractors a program memorandum with instructions on how to implement any changes included in a new regulation. The contractors then incorporate these program memorandum changes into their manuals.

Manual Issuance

The Health Care Financing Administration also distributes and updates manuals that provide guidance to Medicare contractors and providers.

Coding

The Medicare prospective payment system for acute care hospitals relies on hospitals to correctly code patients' diagnoses for Medicare payment. A panel of representatives from HCFA, the American Hospital Association, the American Health Information Management Association, and the National Center for Health Statistics Coding makes recommendations concerning coding policy. HCFA includes major coding changes in the annual prospective payment system regulation. The panel publishes a quarterly report, the Coding Clinic, which hospitals obtain from the AHA.

This quarterly report includes smaller coding changes and clarifications.

Medicare pays for laboratory services in hospital outpatient departments according to a fee schedule. The fee schedule stipulates Medicare payment for each lab service and "panel", or group, of services. In billing Medicare, the hospital uses codes to indicate the lab services provided.

A panel organized by the American Medical Association (AMA) with members from physician specialty societies and a HCFA representative maintains and updates the laboratory codes. HCFA incorporates the panel's coding changes into its current policy.

MEDICARE PROGRAM INTEGRITY

Ensuring the integrity of the Medicare program requires the efforts and coordination between several Departments. The Health Care Financing Administration has adopted a strategy to deter fraud in the Medicare program. We also have a process for handling honest billing mistakes.

This committee has expressed particular interest in civil and criminal prosecution for Medicare fraud. HCFA as an agency does not prosecute providers. If HCFA or one of HCFA's contractors suspects a provider of fraudulent activity, HCFA or the contractor refers the case to the OIG. The OIG then evaluates whether the case should be referred to the Department of Justice.

Billing Mistakes

If hospitals make billing errors, we want to find those errors, preferably before we make payment. We are significantly increasing our efforts to screen claims before they are paid, to review them afterwards, and to audit providers with billing patterns that are out of the ordinary. And, we are using increasingly sophisticated claims analysis software to search out unusual billing patterns that suggest where we need to take a closer look. Our decision to refer a case to the OIG may be in response to several factors including beneficiary complaints, unusual billing patterns, tips from law enforcement, and cost report audits.

If we find errors after we make payment, make no mistake about it, we do want the money back. But we are not looking to put anyone in jail for honest mistakes, and we are not going to refer hospitals to the OIG for occasional errors.

Health Care Financing Administration Fraud Strategy

The Health Care Financing Administration employs a four-part strategy to deter fraud and abuse. The strategy focuses on prevention, early detection, coordination, and enforcement.

Prevention means paying right the first time, the most desirable approach. Prevention is the best means to guarantee the initial accuracy of both claims and payments, and to avoid having to "pay and chase", a lengthy, uncertain and expensive process. HCFA is committed to making Medicare rules as clear as possible so that providers may bill correctly and with confidence.

Early detection is the second key ingredient of our approach. We can identify patterns of fraudulent activity early by using data to monitor unusual billing patterns and other indicators of the integrity and financial status of providers, promptly identifying and collecting overpayments, and making appropriate referrals to law enforcement. I would like to emphasize again that if we find errors, we want the money back. But whether any further action is warranted should be determined by the facts and circumstances of each case.

Coordination with our partners is another important way we can maximize our success. We share information and tactics for fighting fraud and abuse with the States, the Department of Justice, including the Federal Bureau of Investigations (FBI), and the private sector.

When we do find "bad apples" among our many good providers, we take enforcement action against them, including suspension of payment, referral to the OIG for potential exclusion for the program, disenrollment, collection of overpayments, and imposition of civil monetary penalties. Investing in prevention, early detection, and enforcement has a proven record of returns to the Medicare Trust Fund. Medicare Integrity Program alone saved an estimated \$7.5 billion in FY 1997 - mostly by preventing inappropriate payments--through audits, medical reviews, and ensuring that Medicare does not pay for claims owed by private insurers.

Department of Justice and HHS OIG National Studies

The DOJ and OIG may embark on a national study of a particular issue or provider without a referral from HCFA. The DOJ and OIG work directly with the Medicare contractors and intermediaries to collect necessary data for their national projects.

CONCLUSION

We have an obligation to the American taxpayer to take fraud and abuse in the Medicare program seriously. Although HCFA does not prosecute providers, we recognize that the False Claims Act represents an important tool for our law enforcement partners. We must have its substantial penalties if we are going to put an end to deliberate improper billing practices. Without its substantial penalties, fraud and abuse would become even bigger problems than they are today.

We also have an obligation to treat providers fairly. If providers make billing errors, we want to find errors before we make payment or get our money back. But, let me say again, we are not looking to put anyone in jail for honest mistakes, and we are not going to refer providers to the Inspector General for occasional errors. I would be happy to answer any questions you may have.

Testimony of Terry L. Cameron, Health Care Billing Consultant

April 28, 1998

Good morning, Mr. Chairman. I am Terry L. Cameron, healthcare industry professional with over ten years of experience working for major healthcare organizations. I am currently employed in the private sector of healthcare information. I would like to thank the committee for inviting me to speak to you today.

[Three points; compliance, decision to ensure same, do not weaken]

I am here today to talk about generally three points. First, despite the volume of regulations governing Medicare payments, it is possible for every claim to be in compliance. Second, there are some hospitals that are now making the conscious decision to devote the effort and resources to ensuring compliance. But in contrast, there are also hospitals that are not devoting the effort and resources to ensuring compliance. Third, the False Claims Act should not be weakened because any reduction of the enforcement of the False Claims Act could encourage more non-compliant claims to be submitted to Medicare.

For over ten years I have directed the activities of accounts receivable, reimbursement, managed care contracting and compliance operations for a number of teaching physician, and for-profit non-teaching institutions in the healthcare industry. I have had the opportunity to play an instrumental role in the development of billing compliance strategies during my tenure at each institution.

Healthcare organizations are very complex. The hospital or physician group may for instance, have fragmented organizational structures, which results in little control over policies and procedures. It's not uncommon to see as many as a dozen billing systems in one healthcare organization. The organizations that have managed to centralize and re-engineer their fragmented billing practices have been successful in complying with government regulations.

Developing a billing compliance strategy to meet federal healthcare payment requirements takes a tremendous amount of support from within an organization. Senior management must be committed to understanding billing regulations, and willing to deploy an ongoing compliance program. There is software and rules engine technology on the market today which makes it possible for hospitals and teaching physician groups to standardize and comply with government and commercial payer billing regulations. Whether the regulations are related to lab unbundling, 72 hour window, teaching physician guidelines or any other federal billing requirement, if technology and a willingness to change current processes are deployed every claim can be billed correctly.

Prior to the more recent OIG, HHS and DOJ scrutiny, some healthcare organizations made management decisions not to allocate the resources necessary to bring their billing operations into compliance. Although the billing operation is the lifeblood of each and every hospital and physician group, the financial and personnel resources to run the operation effectively, while complying with all carrier-billing regulations, were not always committed. In business, we make decisions based on two things cost and benefit. There is a cost to re-engineering, automating or simply standardizing the healthcare billing process to meet compliance guidelines. But it can be done, and is in fact, being done throughout the nation. And in most cases, the changes will save money in the long run.

[Claims submission, no errors]

The federal health care payment system involves hundreds of pages of law and regulations. However, I know from experience that hospital and provider organizations can comply with federal and commercial claims submission guidelines.

American Express has not made a single mistake on my monthly statement in the ten years I have been a card member. Regardless of whether I travel to Washington D.C., Puerto Vallarta, or London, the charges I make are always correctly detailed at the end of every month. The reason? The banking industry came together over two decades ago and determined how financial transactions should be structured. The lack of standardization of hospital and physician billing makes it sometimes difficult, but not impossible, to similarly comply with billing rules.

There is a need within the healthcare industry to standardize the rules associated with claims payment. To insist, however, that current rules, some of which have been on the books for decades, are too complicated and impossible to comply with is hard to imagine. I have worked for organizations that were willing to commit the necessary resources, and successfully implemented processes to comply with federal payment regulations, so I know it can be done.

Drastically reducing the core enforcement tool of the False Claims Act with legislation is not the solution. In my own experience, I used the False Claims Act to educate upper management regarding the importance of dedicating necessary resources to comply with government regulations. Every decision in healthcare or any other business as I said before is a cost benefit. You have to weigh the pros and cons. The current False Claims Act was a powerful catalyst when I had to discuss the consequences of non-compliance with senior management. When fully informed of the possible fines and penalties, organizations typically take the high road and allocate the necessary resources. Any weakening of the False Claims Act will dramatically affect the chances that upper management will take regarding crucial compliance programs.

I am here today as an expert on healthcare compliance, and as a strong supporter of the False Claims Act. The Act, has increasingly demonstrated its need and effectiveness since its revision in 1986. The recent increase in health care related cases suggests that without a strong False Claims Act, the health care industry is unlikely to change its complicated and often times fragmented organizations to comply with governmental regulations.

Self-policing and weakening the enforcement capabilities of the False Claims Act is not the answer. We should be concentrating on standardization, re-engineering processes and using technology to get claims out the door correctly each and every time.

I appreciate the opportunity to appear before this committee today to share my views and welcome any question you may have.

Testimony of Ruth Blacker, Member, AARP National Legislative Council

STATEMENT of the AMERICAN ASSOCIATION OF RETIRED PERSONS on HEALTH CARE INITIATIVES PURSUED UNDER THE FALSE CLAIMS ACT THAT IMPACT HOSPITALS

Presented by RUTH BLACKER Member, AARP National Legislative Council

Good morning. My name is Ruth Blacker from Guntersville, Alabama. I am a member of the National Legislative Council of AARP. I appreciate the opportunity to testify before the Subcommittee today.

Fraud and abuse in the health care system affect all Americans by increasing the costs of the programs providing care, and the Medicare program is no exception. The public is, justifiably, very concerned about the effect of fraud and abuse on the Medicare program and on the cost and quality of the care they receive. This public concern - even outrage - coupled with accounts of how much Medicare fraud and abuse could be costing taxpayers and the American public, have led the Congress in recent years to expand statutory authority and increase resources to deal with the problem.

The problem is not always a simple one to tackle, however. For example, the sheer number of Medicare claims that are processed annually, approximately 800 million in 1995, makes scrutinizing them for irregularities a complex undertaking. This enormous volume of claims must be reviewed to determine which irregularities are appropriate and which are not. Determining which are fraud and which are abuse is also necessary, because they are sometimes dealt with differently under the law. In addition, it is critical to recognize throughout this process that most providers are honest and, in fact, have an investment in the Medicare program and in it being run efficiently.

THE FALSE CLAIMS ACT

The False Claims Act (FCA) is a critical tool for fighting fraud and abuse in government programs, including the Medicare and Medicaid programs. It should not be changed. Federal enforcement authorities have relied on it to recover hundreds of millions of dollars in improper payments to the Medicare program in recent years. It has also served as a strong deterrent to fraud and abuse. In light of the financial stress Medicare is currently under, these efforts are important to maintaining the solvency of the program.

The False Claims Act authorizes the Department of Justice to seek treble damages against those who submit false claims to the Federal government. It also permits private individuals to initiate qui tam suits against persons submitting such claims and to share in any recovery that is obtained. These two features establish strong incentives to pursue fraud and abuse. Although the Social Security Act contains its own provisions for punishing those who submit false claims to Medicare and Medicaid, the penalties authorized by these provisions are generally less severe than those under the FCA.

Taken together, these two bodies of law provide enforcement officials with a spectrum of possible sanctions to impose, depending on the seriousness of the violation.

AARP applauds the action Congress has taken in recent years to strengthen enforcement tools and to provide additional resources to fight fraud through provisions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Balanced Budget Act of 1997 (BBA). These provisions, which include establishment of a new section of criminal law specific to health care fraud, creation of a health care fraud and abuse control board and account, and increased penalties and fines, will make it easier to identify, prosecute, and punish unscrupulous providers. However, none of these are likely to play a more important role in recovering improper payments or in acting as a deterrent than the False Claims Act.

THE PUBLIC'S CALL TO REDUCE FRAUD AND ABUSE

Despite the major drive by enforcement authorities in the past few years, a 1997 survey by AARP indicated that 80 percent of Americans are unaware of any efforts to combat health care fraud. Of those who are aware, nearly one-third believe that such efforts

have had no effect. Moreover, the public remains pessimistic about the government's ability to fight fraud.

The public also believes that reducing fraud and abuse will increase the quality of their care and lower their costs, and that more can and should be done to reduce fraud in the health care system. Perhaps most important, there is a widely held perception among the public that if fraud and abuse were curbed, this could keep Medicare solvent. While this is a misperception, it colors the public's willingness to seriously consider the tradeoffs that will be required to achieve long-term fiscal viability in Medicare.

RECENT USE OF THE FALSE CLAIMS ACT

It is AARP's understanding that the hospital industry has recently come under unprecedented scrutiny by the Department of Justice (DOJ) through a series of national projects involving use of the False Claims Act. These projects have been looking specifically at hospital billing practices with regard to the 72-hour DRG "window," outpatient laboratory tests, and physician services provided by residents in teaching hospitals.

In carrying out these projects, in many cases the first step that DOJ took was to issue "demand" letters informing hospital administrators that they believed fraudulent billings were submitted by their institutions in violation of the False Claims Act. These letters urged the hospitals to pay damages to settle the dispute quickly and to not risk further action, fines, and possible exclusion from the Medicare program under the FCA.

Hospitals saw these letters as intimidating and beyond the intent of the law.

Because fraud and abuse have a very real impact on Medicare, we believe that federal law enforcement officials need to have adequate authority to pursue those who take advantage of the program. However, this authority also carries with it a responsibility for enforcement authorities not to take short cuts in pursuing fraud. Among other things, this would include making a good faith effort to distinguish cases involving real fraud and abuse from those involving honest mistakes or misunderstandings, and giving the providers and health professionals that treat Medicare beneficiaries some idea about how prosecutors will use the False Claims Act in individual cases.

Providers, however, have the responsibility to remain up-to-date on current billing regulations and to maintain a competent staff to avoid billing mistakes and subsequent improper payments. Such improper payments - whether honest mistakes or fraudulent claims - cost Medicare significant amounts in inappropriate payments. The extent of fraud and abuse in Medicare - whether real or perceived - also contributes to diminished public confidence in the Congress' stewardship of taxpayer dollars and in the Medicare program itself.

MAINTAINING A STRONG FALSE CLAIMS ACT

AARP is deeply concerned about the effect that proposed legislation would have on the False Claims Act. We believe such legislation would seriously undermine the FCA, making it much easier for unscrupulous providers to successfully submit fraudulent Medicare claims, and remove an important incentive for providers to take great care to see that their billings are correct.

The legislation would establish a series of major exemptions from civil liability under the False Claims Act for fraud perpetrated by providers supplying health care services under the Medicare program. Through its retroactive application it would also protect those companies with enforcement actions already well underway.

In particular, the legislation would amend the FCA to excuse from civil penalty such practices as overbilling, double billing, and billing for unnecessary services or services

not provided, so long as the amount for any particular scheme is not "material." Thus, in an environment where there is intense public concern about the need to reduce fraud and abuse, Congress would be changing the law to create a "loophole" that would protect hospitals and other providers from prosecution under the False Claims Act if the amount fell below a certain threshold. For huge corporate providers who process millions of claims and receive billions from Medicare, the chance of misuse of such a "loophole" is far too great a risk - hundreds of millions of dollars in improper payments could be at stake.

In addition, the legislation would impose a far heavier burden of proof on the government for civil cases pursued under the FCA. Changing the evidentiary standard from "preponderance of evidence" to "clear and convincing evidence" would make it more difficult, and in some cases impossible, to prove fraud.

In light of recent Congressional actions to strengthen the government's hand against fraudulent health care providers, it would seem contradictory for Congress to take action on a bill that would reduce the tools that federal law enforcement officials have at their disposal to identify and prosecute fraud and abuse. AARP strongly recommends that the Congress not make changes to the False Claims Act.

The FCA is, however, a very powerful tool, and when used inappropriately could have a corrosive effect on honest providers' sense that they are being fairly treated by Medicare and federal law enforcement authorities. In this regard, we understand that the FCA projects undertaken by the Justice Department have created problems for legitimate providers. We are encouraged by the fact that the Department has shown a willingness to reevaluate and revise its procedures for using the FCA, and that it has offered assurances that it is not pursuing honest billing errors or simple mistakes. These steps will require ongoing oversight to ensure that they strike an appropriate balance, but we are pleased that initial steps have been taken to address legitimate concerns of the hospital industry.

It would not be appropriate or necessary for Congress to change the False Claims Act in order to deal with problems in its implementation. It would make sense, however, for standards to be established to guide enforcement authorities with carrying out this responsibility. This does not require a change in the law, but important to this effort is the need for enforcement officials to consult with program officials, as well as with the organizations representing providers and health professionals, as they develop policies to guide the exercise of prosecutorial discretion, and avoid excess.

CONCLUSION

The False Claims Act must remain intact and be used appropriately to continue to preserve and protect the Medicare program for the American public. The most recent audit by the Department of Health and Human Services Office of Inspector General (OIG) shows that progress is being made in stemming fraud in the Medicare program, but there is still a long way to go. As we become better at identifying and rooting out the "easy fraud," it becomes more difficult to distinguish among fraud, honest mistakes, and justifiable anomalies in billing. This is not a time for tying the hands of enforcement authorities by weakening the False Claims Act, there is too much at stake. At the same time, however, it is very important that this powerful law be used judiciously by enforcement authorities.

End Note

There is no kind of dishonesty into which otherwise good people more easily and frequently fall than that of defrauding the Government.

Benjamin Franklin

To summarize; the crux of the problem seems to be that health care providers are expected to employ free-market profit maximization techniques in a government program. No wonder fraud occurs.

Here is a solicitation right off the Internet that indicates the profit maximizing aspect of the Medicare business:

The Medicare/Medicaid Library provides essential information to help you achieve compliance and maximize reimbursement revenue. The library is an essential resource for hospitals, medical practices, insurance companies, law firms, accounting firms, health care consultants, and government agencies.

The Medicare/Medicaid Library includes:

IHS and Healthcare Financial Management Association Newsletters

Legislation (reimbursement-related laws and proposed legislation)

Code of Federal Regulations

Federal Register Notices

CHAMPUS/CHAMPVA Manuals

Codes and Fee Schedules

Administrative Decisions and Court Cases

Federal Government Reports

Federal Government and Industry Related Publications

To order this product or for a free trial, please contact a Sales Representative at **1-800-xxx-xxxx** or complete a Product Information Form.



A workable system is needed that will balance the public's interest (helping the financially disadvantaged and infirmed with taxpayer-funded medical care) with the need to turn a profit in business.