

**NAVIGATING THE NEW PART “D”
PHASE OF THE MEDICARE PROGRAM**

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I

INTRODUCTION AND BACKGROUND

A. A Brief History of the Medicare Program.

Government health insurance for the elderly did not have its debut in America, but rather in Prussia in 1883 under the authoritarian regime of Otto von Bismarck. Bismarck invented mandatory health insurance and social security to keep his subjects subservient and dependent, to prevent the more leftist socialists from gaining popular support, and to help cover the costs of the Franco-Prussian War through payroll taxes masked as retirement savings accounts. His legacy had a huge impact worldwide at the turn of the century, as many countries began adopting similar programs.

In 1939, during his first year as a United States Senator, Claude Pepper introduced a bill that would provide medical benefit reimbursement payments to elderly Americans under specified conditions. It took from 1939 to 1965 for Senator Pepper's dream to become a reality, when President Lyndon Johnson signed into law a series of amendments relating to Social Security that collectively established the new system known ever since as "Medicare."¹

In its first year, Medicare payments totaled \$1 billion, but by 1971, the payments had already risen to \$7.9 billion annually. Congress was surprised by the ballooning costs of health care services, and held hearings and established commissions to fix the problem, the first of several failed attempts. Even with seven payroll tax hikes in twenty-one years, anti-"fraud" regulations, and other reforms, Medicare is still a disaster. Despite a \$150 billion annual

¹ It was perhaps a harbinger of things to come when the first person to enroll in the new Medicare program, attended by great fanfare, was Walter Brennan, the then-well-known movie actor, Oscar winner, and television star. It seemed to occur to relatively few people at the time that Brennan, a multi-millionaire several times over, needed publicly-financed health insurance coverage about as much as Tiger Woods could use a few lessons at golf.

Medicare budget, today's elderly now spend more than twice as much out of pocket than they did before Medicare was enacted, even after accounting for inflation. Seniors who try to circumvent the system by opting out of Medicare altogether must forego all Social Security benefits. The price of healthcare for the elderly has continued to increase, even as Congress passed more and more reforms, further inundating doctors with paperwork and new regulations, and increasing payroll taxes for workers.

B. The Debate Over, and Introduction of, Coverage for Prescription Drugs.

Prescription drugs have been especially expensive for seniors, in part due to the Food and Drug Administration (FDA), which forces drug companies to spend hundreds of billions of dollars to test their drugs before releasing them onto the market, even when such drugs are often freely available and safely used in Europe. In order to recoup these costs, at least their argument goes, pharmaceutical companies must charge exorbitant prices.² In the meantime, several studies have concluded that far more deaths result from the FDA keeping drugs off the market than lives saved from this "protection."

In the meantime, it has also become true over the years since Medicare was enacted in 1965, there has been a marked increase in the availability of sophisticated medications that treat countless chronic diseases such as diabetes, hypertension, and heart disease. Existing drug regimens are now more target-specific and minimize side effects and decrease negative risk factors. Prescription drugs now comprise a much more significant component of medical care, especially for the elderly population, than when Medicare was first put into place in 1965.

² Not too many tears need to be shed for drug manufacturers; in the most recent year for which comparative figures are available, these companies had the greatest return on revenues, reporting a profit of 18.5 cents for every \$1 of sales, which was 8 times higher than the median for all Fortune 500 industries, easily surpassing the next most profitable industry, which was commercial banking with a 13.5% return on revenue.

In an attempt to alleviate the effects that high drug prices were having on citizens, particularly the elderly -- not to mention that the desire for federally funded prescription drug benefits had long ranked high in public opinion polls attempting to gauge the public mood -- Congress enacted into law the largest expansion of Medicare since its establishment in 1965. Coverage under the new law began to become available on January 1, 2006. The new provisions are now commonly referred to as Part “D” of Medicare -- “D” standing for “drugs.” More than just a few observers have said a better appellation might be “disaster” or “debacle.”

The legislative history that preceded the adoption of new Part D was not especially pretty. The new law was signed by President Bush on December 8, 2003, after barely passing in Congress. One month later, the ten-year cost estimate originally offered by the backers of the new program was boosted to \$534 billion, up more than \$100 billion over the figure presented by the Bush administration during Congressional debate. The inaccurate figure helped secure support from fiscally conservative Republicans who had promised to vote against the bill if it cost more than \$400 billion. It was widely reported at the time that administration officials had concealed the higher estimate and threatened to fire government analyst Richard Foster if he revealed it.

C. Goals of the Reformed Prescription Drug System.

Known formally as the “Medicare Prescription Drug Improvement and Modernization Act (MMA), the new law was enacted as Public Law § 108-173. The primary goal of the legislation was to alleviate the strain on the state-based Medicaid systems by making available outpatient drug coverage, sponsored by the federal government through Medicare, with much greater opportunity for feedback from the public and through a system that is considered voluntary. The concept that the new program should be a “voluntary” one driven as much as

possible by market forces turned out, when the legislation was cast into its final form, to be unrealistic because of the existence of “dual eligible beneficiaries.” A dual eligible beneficiary is a party eligible for coverage under both Medicare (42 U.S.C. § 1395) and the Medicaid program of the state in which they reside (*Social Security Act*, Title XIX; 42 U.S.C. § 1396); currently, this segment contains approximately 6.4 million populants. For these individuals -- many of whom reside in skilled nursing facilities and other types of residential care -- there are no decisions to make: The extent and nature of coverage by new Part D is dictated by the law. (Many special problems are created by the existence of dual eligibles; see Section #4C below.)

D. Historical Efforts to Include a Prescription Drug Benefit in Medicare.

The health care system has been unsuccessfully grappling with developing a system for covering outpatient prescription medications since the implementation of Medicare and Medicaid. In 1969 a federal task force on prescription drugs was appointed to report issues make recommendations; its efforts ultimately amounted to nothing. In 1988 there was a very short-lived Medicare Catastrophic Coverage Act (MCCA) formulated. The principle component of the MCCA allowed Medicare to cover the catastrophic costs of prescription drugs through a monthly premium of \$4 and a fifteen percent surtax on the federal tax liability of Medicare enrollees with tax liabilities over \$150. The projection was that only 36% of enrollees were expected to owe anything at all. The MCCA effort failed, in part due to the confusing nature of the program, and would have failed in any event had anyone seriously tried to implement it because of its inherent analytical and computational flaws. Then, in 2002, the Republican-sponsored bill H.R. 4954 passed the House of Representatives in a narrow 221 to 208 vote, while several competing proposals languished. Throughout the time period between the signing of MMA and its intended implementation date of January 1, 2006, there was very little dialogue between those who would

have to administer the program, on the one hand, and from those in the long term care sector who would be stuck with its consequences, on the other hand. The owner of Stonebridge Pharmacy, an industry leader in the long term care pharmacy business, was quoted as saying that “it was not until February of 2005 [less than one year from the start of Part D] that Congress asked for the long term care pharmacy input to any significant degree.”

E. Summary Overview of the New Program and Congressional Intent.

The design of the new prescription drug benefit is in some respects similar to Medicare Part B. It features an optional benefit in return for a premium within the context of a system that is considered voluntary. Congressional intent was to provide for a system driven to a large extent by market forces operating within the private sector, delivered through a network of private prescription drug plans (PDPs); or through Part C in conjunction with an HMO or Preferred Provider Organization (PPO) that covers drugs as well as other benefits; or through the Medicare Advantage Program that includes a Part D benefit (MA-PD).

II

**THE INCREDIBLE MAZE PRESENTED
BY PART D OF THE NEW PROGRAM**

A. The Inherent Complexity of the Program -- in General.

By far the most often expressed objection voiced by critics of the new Part D program has been its complexity. One commentator provided the following example that illustrates the fundamental nature of the underlying problem:

“Regardless of your current prescription drug coverage, you are encouraged to review the full range of choices that may be available to you. It is a daunting task requiring hours of research.

For example, if you live in Pittsburgh, Pennsylvania, located in Allegheny County, you'll find 20 firms selling more than 50 prescription drug plans -- this includes the approximately 25 plans offered through Medicare, as well as the various 'creditable' plans that are offered outside of Medicare. Choices will vary by county, and some areas offer more than 100 choices."

In order to fully understand the implications of Medicare's recently-introduced prescription drug benefit, it is first important to summarize the most important aspects and requirements embodied within the new law. The lack of the public's ability to understand "The System" is a direct result of its complexity, and is illustrated by the fact that *of the seven million people eligible for the new January 1, 2006 coverage, only 661,000 were signed up by mid-December, 2005*. Admittedly, this statistic has since improved. Approximately 42 million Americans receive Medicare. Under the new prescription drug program, they have until May 15, 2006 to choose from dozens of plans offered by insurance providers and other companies. Bush administration spokesmen have recently expressed confidence that by the deadline, between 28-to-30 million participants will have signed up; as of this writing, the number stands at 8.1 million.

Medicare publishes a 92-page booklet entitled "Medicare & You." Written in the same kind of governmental prose that characterizes, for instance, Treasury Regulations under the Internal Revenue Code, it is difficult to picture just how this publication is going to be of much *real* assistance to the elderly who need it most.

B. Determining Who is Covered Under the New Program.

In an effort to sort things out, it is useful to begin by saying that most everyone covered by the new law fits into one of five separate categories, and that it is important to determine what category applies before proceeding with further analysis. The categories of beneficiaries are:

- *Original Medicare Plan Only:* The original Medicare plan does not provide prescription drug coverage. For people who have Medicare but no drug coverage, the new law affords them the opportunity to obtain coverage. Those who make this election must join a Medicare drug plan, join a Medicare Advantage Plan (which offers medical and drug coverage), or joining another plan (such as a state-specific plan or low-income plan).
- *Medicare and Medigap Supplemental Insurance:* New Medigap policies for prescription drug coverage will no longer be sold after January 1, 2006. Individuals can keep their current coverage, but Medicare recommends that the better course is to join a plan that offers a Medicare drug benefit and then drop the supplemental policy.
- *Employer/Union-Provided Prescription Drug Coverage:* Coverage providers are supposed to send their insureds a comparison that highlights the differences between a person's current coverage and the standard Medicare prescription drug coverage. Those who are satisfied with their current coverage may keep it and take no action. But those who are dissatisfied with their current coverage need to find new coverage.

- *Medicare Advantage Plan:* Within this category exist a vast menu of plans and coverage options, nearly all of which have been changed by the new law. Comparison shopping is left completely up to the consumer.
- *Medicare and Medicaid:* Individuals who have coverage from Medicare together with Medicaid drug coverage will automatically get comprehensive prescription drug coverage from Medicare beginning January 1, 2006. These individuals need to either choose a prescription plan, or one will be chosen for them.

C. Determining to What Extent Coverage Extends Under the New Program.

While the variations seem practically endless, there are four basic categories of prescription drug plans that will qualify under new Part D. These are:

- *Original Medicare and a Medicare Prescription Drug Plan:* Participants under this option pay one premium for the Medicare coverage and a separate premium for their drug plan.
- *Medicare Advantage Plan:* Participants obtain drug and medical coverage from one plan in return for one premium. Plans come in a dizzying array of choices, including health maintenance organizations (HMOs) and preferred provider organizations (PPOs). Many plans offer multiple tiers, with a panoply of coverage and premium structure.
- *Other Medicare Plans:* Plans like, for example, the “Program of All-Inclusive Care for the Elderly” (“PACE”) provide drug and medical coverage, but are not considered to be Medicare Advantage plans.

- *Medicare Private-Fee-for-Service*: This is private medical insurance that is accepted by Medicare-approved doctors. This type of insurance may or may not include coverage of all or some prescription costs.

D. Applying the “Formulary” Rules.

A prospective beneficiary who figures out which of the five categories into which he or she fits, then determines what category of plan seems most suitable, is unfortunately not yet even close to arriving at a final determination of what options will best fit his or her interests. Each plan has a “formulary,” which is really just another way of saying “a list of drugs.” A particular plan’s formulary may include the medications you routinely take; another’s may not. Worse still, a particular plan’s formulary may take into account only *some*, but not *all*, of the medications prescribed for you. Even though even then no truly universally beneficial solution can in many cases be attained (because of the disparity in each beneficiary’s required drugs versus the wide variety of formularies offered by different plans), the existence of the formulary component in new Part D at the very least necessitates the checking of every available list by each separate beneficiary.

The formulary rules summarized above probably already sound bad enough, but in fact, new Part D makes them even worse: Formularies can change every year, so just when you thought you had the right plan all signed up, the next year’s changed formularies may dictate that you find a different plan. The average formulary as of this writing typically exceeds 1,200 separate drugs per provider.

E. Plan Expenses.

Every plan carries with it expenses; the only question is how these will be paid.

Some plans charge a fee on top of the \$78.20 Part B fee (2005 rate); others include that Part B fee in their premiums. Premiums vary widely based on coverage. Besides plan premiums, the majority of plans also charge a deductible, or “co-pay,” for prescriptions.

There is also available what is known as the standard Part D program, under which enrollees pay a \$250 deductible, and then 25% of prescription drug costs until annual out-of-pocket costs reach \$2,250. Any costs over that amount, up to \$5,100, are paid 100% by the Part D enrollee. This gap is known in the trade as a “doughnut hole,” since the beneficiary gets something on each side, but nothing in the middle. Beneficiaries who require either a large number of prescriptions, or a small number of comparatively expensive prescriptions, can quickly find themselves drowning in the batter left over from the doughnut hole.

F. Private Plans.

Some private insurance plans are expected to cover \$2,000 in drug expenses in 2006. After that, the beneficiary pays all costs until expenses reach \$3,600, at which point catastrophic insurance coverage will pay 95% of future costs. These plans, like all others, have differing provisions; some have no doughnut holes at all, while others have doughnut holes of varying sizes.

G. Time Pressure Within Which to Make a Choice.

As in the case of Medicare Part B, Medicare Part D comes with built-in penalties for signing up after the initial enrollment period has expired. The window for 2006 expires on May 15th of that year³. After initial enrollment, beneficiaries have a six-week window each year within which to change plans (November 15th through December 31st).

³ As of this writing Congressional efforts are underway to attempt to extend the current May 15, 2006 deadline through December 31, 2006. The fate of these attempts cannot be predicted with any certainty at this time.

After May 15, 2006, when the initial enrollment deadline ends, no one who was already on Medicare prior to March 1, 2006 may enroll until the next annual enrollment period, which is not until November 15, 2006. Also, if a person is eligible and did not enroll or have other creditable coverage, they will incur a 1% per month add-on fee for the remainder of the time the beneficiary remains on Medicare Part D.

H. The Anomalous Role of the States.

Even though the federal government is financing the bulk of Part D's costs, estimated at somewhere between \$534 billion and up to approximately \$1.3 trillion dollars over ten years, depending on who is doing the calculating, the states still retain considerable responsibility for the costs of this monumental program. The states are mandated to incur a monthly "clawback" (to partly finance the dual eligible beneficiaries eligible for both Medicare and Medicaid), which approximates 90% of what they would be responsible to pay for the dually eligible under the Medicaid plan alone. The states are also responsible to determine eligibility for the low income subsidy, and if they elect, pay for wrap-around coverage for those medications that are not approved under the suggested Medicare D formulary. Additionally, many states have elected to cover some of the transition medications earlier on in the program, due to what amounted to a crisis during the first quarter of 2006 when people who badly needed medication still had not figured out how to sign up for coverage under the new law.

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IV

SPECIAL PROBLEMS WITH WHICH SKILLED NURSING FACILITIES AND OTHER FORMS OF RESIDENTIAL CARE FOR THE ELDERLY WILL HAVE TO CONTEND UNDER NEW CHAPTER D OF MEDICARE

A. In General.

Seen from the perspective of a skilled nursing facility administrator, from the onset the new program embodied by Part D failed to specifically address various fundamental needs and characteristics of skilled nursing facilities, and has also greatly expanded the administrative responsibilities of such facilities. New Part D has also increased the potential liability of nursing home facilities by imposing impediments that interfere with such facilities' ability to assure timely and regular access to each resident's prescribed medications.

B. The Dilemma Presented by the Legal Obligations of Skilled and Other Nursing Facilities.

Under 42 C.F.R § 483.60, a skilled nursing facility must "Provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement..." as part of the agreement for participation in Medicare and Medicaid, which comprise by far the largest portion of skilled nursing facility financing. Essentially, the facility must supply all the medications and biologicals prescribed by the medical staff to meet the needs of every resident or risk losing their certification for continued operation, even if the facility must itself assume the payment for the prescription medications. The facility Administrator, who is duly licensed by the state and is charged with ensuring the safety and security of the residents, is ultimately responsible to ensure compliance with the statute and that the policies and procedures accurately reflect the proper medication administration protocol.

(Outside the acute care arena, Medicare has never covered medications, thereby creating a situation whereby the lack of availability of affordable prescription medication has caused many Medicare beneficiaries to utilize the substantially more cost-prohibitive hospital system for treatment. The hospital costs far outweigh the cost of providing a consistent drug regimen. But left with no choice, many prescription drug-dependent patients have discovered that entree into the healthcare system via the Emergency Room -- a place where, by law, a patient cannot be turned away irrespective of inability to pay -- is literally their last resort.)

C. Special Problems Created by “Dual Eligibles.”

(1) In General.

As previously mentioned, a “dual eligible” is someone who is eligible for both Medicare and Medicaid. Approximately 6.4 million individuals make of this segment of the Medicare pool. These individuals pose special challenges for skilled nursing facilities and other residential treatment centers, and most of these challenges have either been created, or at least exacerbated, by the adoption of MMA.

The 6.4 million dual eligibles represent the vast majority housed and cared for within the nation’s skilled nursing home facilities. With the onset of Part D, there is a new emphasis on the payer status of each skilled nursing facility resident, placing them into categories that ultimately determine their access to medications as well as their choice of prescription drug plans. They are characterized as being more vulnerable than their community counterpart in that they are: six times more likely to have an income of less than \$10,000; four times more likely to have less than a high school education; and six times more likely to live in an skilled nursing facility.

**(2) Government’s Preemption of What Were Supposed to Be the
“Market-Driven Choices” of Dual Eligibles.**

The fashion in which Part D of MMA has been made available to dual eligibles through governmental channels differs markedly from the originally stated goal of affording individuals “choice” in their health care decisions.

The dually eligible beneficiary in a nursing facility is not afforded the same decision-making opportunities as the non dually-eligible. This sector of Medicare beneficiaries have no choice but to participate in the program or lose their entire complement of Medicaid services. The plan is clearly involuntary and coercive, and the affected beneficiaries’ PDP choices are limited to a select group as well.

Beginning in late October, 2005, CMS began sending out all dually eligible nursing home residents a yellow letter identifying what PDP they would be auto-enrolled in (the “Yellow Letter”). In order to “level the playing field” and afford each PDP an equal chance of gaining the enrollment of the dually eligibles, CMS assigned them randomly to a particular PDP. These procedures were implemented without any input from the beneficiaries, without any consideration of what prescription medications they were currently on or would likely be on in the future, or even the formularies (drug lists) of the PDPs.

In New York State, there were fifteen PDPs that were eligible to be assigned to the dually eligible residents, based on a benchmark premium of \$29.83 per month. There are over one hundred dually eligible residents residing in nursing facilities in the New York State, which represents over 90% of the state’s total nursing home population.

According to the Yellow Letter, the dually eligible residents would not have to pay anything out of pocket, not be subject to any premiums, deductibles, gaps in coverage, or co-

pays, as long as they selected or were auto enrolled in a PDP at or below the benchmark premium number. The only dually eligible beneficiaries that were not auto-enrolled were those enrolled in the MD-PD plans.

D. A Recapitulation of the Complexity Along With Other Problems Medicare D Will Impose on Both Nursing Facilities As Well as Other Medical Providers and Patients.

The Yellow Letters were mailed to the Medicare beneficiaries, many of whom were clearly not competent to understand the letters, let alone the implication that if they refused to be enrolled, they would lose their Medicaid altogether -- the resource that pays for their nursing home stay. Moreover, if a beneficiary chose a PDP not within the predetermined benchmark premium, they would be billed the difference. While under the traditional plan, there was never a charge.

An additional restraint on the nursing homes that became quickly apparent is that only the resident or authorized representative, under state law, can advocate for the resident and enroll them or change their auto enrollment designation, e.g., court appointed legal guardians and the holders of Durable Powers of Attorney for health care decisions, provided they have the authority to act for the beneficiary for their health care decision making. Representative payee status (usually designated by the Social Security Administration) is not sufficient. This was coupled with the marketing restriction from CMS that the facilities could not steer the resident to one PDP, possibly causing the nursing facilities to switch pharmacies or, even worse, give birth to a multi-pharmacy system within the facility, because if a resident was on a PDP that was not contracted with a specific LTCP (long term care pharmacy) the facility had to either contract

with a LTCP that did have a contract with that PDP or was responsible for the cost of that resident's prescription drugs.

In order to ensure that the nursing home residents received their prescription drugs, CMS proposed a transition period of at least 90 days. During this period, the drug plans would cover a temporary 90 day supply of drugs, even if they were non-formulary, to give the physician and family members an opportunity to look at the resident's prescription medications and make medically appropriate adjustments.

Once they received the Yellow Letter, the dual eligibles, and any other resident that utilizes Medicare benefits, could select a plan or change plans. On October 17, 2005, CMS posted several PDP plan finder tools at www.Medicare.gov. This formulary finder system can be a handy tool for those elderly patients with access to a computer interconnected to the Internet; who are computer-literate at "web surfing"; and who are comfortable with the idea of entering reams of personal data into a system for which no assured policy practice has yet been put into place by law.

The majority of residents admitted to a nursing facility are covered under Medicaid and, to a less significant degree, Medicare. Under the traditional Medicaid system, the process of obtaining prescription drugs was relatively straightforward. The nursing facility was required to contract with one long-term care pharmacy that would agree to supply the medications on a continuous basis and the facility was responsible to have policies and procedures for the safe storage and accurate administration of prescription medications and biologicals. Each patient's attending physician would be responsible to prescribe the medication and the nursing staff would ensure that the medication was ordered from the pharmacy and subsequently received by the facility. Those residents that were short-term were, for the most part, covered by Medicare Parts

A and B for their short term rehabilitation stay, and would not need to utilize any prescription drug benefit, as under the RUG (rate utilization group) system, the facility was responsible for the payment of prescription medications. The system was routine and for the most part operated successfully without incident.

Additionally, under the traditional system, Medicaid assumed only modest control over the prescription drug distribution system, and it remained within the discretion of the physician to prescribe the medication that he or she felt was most efficacious, regardless of price or waste factor. This lack of monitoring caused moderate waste, e.g. when a prescription medication was increased, the physician would simply order a new dosage card and the old order would be destroyed, even if only one pill was used in a thirty day supply.

Under MMA, there are strict guidelines that each PDP must adhere to in order to be considered eligible to provide prescription drug coverage to eligible enrollees. All PDPs that wanted to be considered to provide the coverage had to submit a formal bid to the Center for Medicare and Medicaid Services (CMS) for the cost of providing the drug benefit to a typical beneficiary in the area they target to serve. The bids were submitted by the first Monday in June for the plans intending to offer the benefit for the following calendar year. The level of risk rebate allocation was \$96.30 for the typical enrollee in 2006, computed as a monthly average. Plans expect to earn a healthy profit by containing costs and negotiating price discounts based on volume and rebates.

Each PDP must be organized and licensed under state law as a risk bearing entity eligible to offer health insurance or health benefits in each state in which they will do business and for every contract year, other than the first, CMS will require a PDP to have a minimum enrollment of at least 5,000 individuals. Additionally, a PDP must offer qualified (as defined by CMS)

prescription drug coverage to all Part D eligible individuals residing in their plan's service area. The PDPs must offer a standard benefit, which is a benchmark plan for Part D enrollees, taking into account the population's drug usage patterns and standards of quality. Under the standard plan enrollees pay the monthly premium, annual deductible, and co-payments. The PDPs will have some discretion to craft their own combinations of benefits and premiums, as long as the plan is actuarially equivalent or exceeds the standard benefit.

Also, all PDPs must provide coverage within CMS guidelines and have a pharmaceutical and therapeutics committee comprised of physicians and pharmacists with at least one member having long term care expertise. A plan must offer at least two medications in each of the 146 unique therapeutic categories and pharmacologic classes, including all or substantially all drugs in the following classes: anti-depressants, antipsychotics, anticonvulsants, anticancer immunosuppressants, and HIV drugs. The PDPs also were required to contract with any willing long-term care pharmacy in their region, provided that they could reach an agreement on the stipulated contracted terms.

Part D covers drugs defined as drugs that may be dispensed only upon prescription and are approved for safety and effectiveness as prescription medications under the *Federal Food, Drug, and Cosmetic Act*, used and sold in the U.S., and used for medically accepted indications. They also include biologicals, insulin, syringes, alcohol, swabs, and some vaccines. Notably excluded are drugs for weight loss, fertility, non-prescription drugs, and vitamins. Plans are allowed to change formulary drugs with sixty days' notice to the affected members and offer an alternative therapy.

The design of the plan is further complicated by a Byzantine actuarial scheme, whereby seniors are expected to understand a complex insurance model where terms like "doughnut hole"

and “risk sharing” would interplay. For the non-institutional (community) Medicare-only recipients, the Part D premium was projected to cost \$35 per month (according to the current literature, it has been adjusted to \$25 per month) and is characterized by an average annual deductible of \$250, of which the enrollee is expected to bear the entire cost. There is a 25% coinsurance for the next \$2,000, for a total responsibility of \$2,250. The enrollee is then responsible for the entire cost (doughnut hole) for the next \$2,850, up to \$5,100. After \$5,100, only a 5% coinsurance is due. There is further a small co-payment (\$1 for generic drugs and \$3 for non-generic prescription drugs).

In order for Medicare beneficiaries to apply for the Medicare Part D, they must currently have either Medicare Part A and/or Part B coverage. The application process is very confusing to most seniors that are not familiar or are not very proficient with the Internet. They have the option of either applying online at www.medicare.com, visiting the individual PDP’s website, or trying to get through the voice-mail system maze common to all governmental bureaucracies by telephoning 1-800-Medicare. Additionally, there is a provision for an extra help subsidy to assist low income individuals to pay for the premium and deductible for those Medicare beneficiaries that meet the strict asset guidelines based on the Federal Poverty Levels (FPL). If a Medicare beneficiary has income that falls under 150% of the FPL (\$1,197/single or \$1,604/couple per month) they should apply for the extra benefit. Applying for the extra benefit is different than enrolling in a PDP, as not everyone who receives Medicare benefits is eligible. After approval for the extra help, beneficiaries still must apply for the prescription drug benefit. The three ways that they can apply for the benefit are:

- Complete form SSA-120;
- Call social security and apply via telephone; or

- Apply online at www.ssa.gov/prescriptionhelp.

Not all Medicare enrollees must join a Medicare PDP as long as they can prove that they have other creditable coverage, considered as current enrollment in a prescription plan that provides coverage that is as good as a Medicare part D plan, as evidenced by a letter given to the enrollee. These are plans can be provided by a previous employer, the federal government, Military (Veterans Association), or State pharmacy assistance programs.

As expected, each PDP has a different formulary within the confines of the Medicare Part D program. As a consumer driven phenomenon and to a large extent a for-profit venture, it is up to the enrollee and his/her physician to verify and ensure that the medication prescribed will be on the individual's PDP's formulary and, if it is not, the correct procedure to undertake to gain access.

CMS has assured the public that if a medication is medically necessary for its indicated use, i.e. not being utilized for an off-label purpose, the PDP must agree to furnish that medication; however, the PDP can establish its very own "procedural matrix." Each PDP must establish and maintain a grievance procedure to address prior authorizations, appeals, and exceptions to denials of coverage. Moreover, a PDP must provide coverage determination in the specified time period (72 hours for a standard coverage determination for a regular appeal or 24 hours for an expedited appeal). If a PDP decides to deny a prescription medication, it must specify in writing the reason and information regarding the right to a re-determination, describing both the standard and expedited re-determination procedures. There are a series of formal procedures that can go all the way to a hearing before an administrative law judge (ALJ), a Medicare appeals council at CMS, and, ultimately, even a United States District Court.

Although the PDPs are required to list at least two drugs in the stated classes, in order to maintain cost control, the privately owned drug plans can restrict the enrollee access to their prescription drugs by: use of prior approvals, step therapy provisions, and volume limits. The use of prior authorization requires that the enrollee or his/ her doctor apply to the plan sponsor for approval before the plan will cover a specific drug. This places significant administrative burdens as extensive documentation is required on the physician's part. While step therapy provisions require the physician to use less costly medications and a variety of different drugs, in place of the medications to which they and their patients may be accustomed, then and only then, when the therapies fail, can the physician switch back to the non-formulary drug. Volume limits restrict the quantity or dosage of the drug that can be prescribed for an enrollee regardless of whether the physician has determined if greater quantities or dosages are clinically indicated.

Additionally, under § 18031, CMS may impose sanctions on PDPs that have entered into contracts to provide Part D benefits and do not adhere to the federal guidelines of participation. The sanctions include civil monetary penalties up to \$100,000 and suspension of the ability to continue offering the Part D benefit.

V

THE PROJECT PHASE OF THE ASSIGNMENT

A. Welcome to the Paperwork Nightmare Called “Medicare Part D.”

The following is an account of my personal experience as a licensed nursing home administrator in a 300 bed, Medicaid and Medicare certified facility located in Westchester County, New York. Through association meetings, networking and conferences, this experience appears indicative of other nursing homes' experience in the first four months of the Part D

program. The financial composition of the resident population in my facility during this period consisted of: 206 residents, representing the 69% of the total facility population that was dually eligible; 47 residents, representing the 16% that were Medicare-only (non-dually eligible); and 44 residents, representing the 15% who were listed as having other (private or HMO) payment sources. The total average population for the time period was 297.

There are approximately 1.7 million nursing home residents in the United States, with 70% of them qualifying as dually eligible. Before January 1, 2006 those residents were totally reliant on Medicaid for their prescription drug needs. The state government would reimburse the nursing homes at a rate that was factored into a daily rate, with an add-on for prescription drugs. On January 1, 2006 this add-on was taken away from the rate (in this facility, \$8.00 per day), or 4% of the total Medicaid rate was eliminated, which would have a total impact of \$613,000 per year.

The drafters of new Medicare Part D did show at least some appreciation of the fact that nursing home residents are in a different category than their community equivalent, in that they are almost entirely at the will of the institution for their medical needs; their decision making ability can be compromised; and their health care needs tend to be greater. Although there were some legislative concessions (the inclusion of a transition period; no required co-pays for the dually eligibles; and the ability to opt out of a plan), it is clear from my experience that neither the PDPs, long term care pharmacies, nor nursing home staffs were ready for the enormous impact that the new Part D legislation would have on their respective operations.

The facility began preparing for Part D in early 2005. At that time I began a dialogue with the current long term care pharmacy and determined that the current vendor was not sufficiently preparing for Medicare Part D, as a result of which he interviewed three larger

vendors: ChemRx, Omnicare, and Stonebridge Pharmacy. I decided that Omnicare was the largest and more apt to respond to the specific Medicare D concerns that the facility would face. The other two vendors had both limited knowledge of Part D and expected the government would amend the current law to make it more nursing-home-friendly, while Omnicare appeared to be preparing and signing up as many PDP contracts as available.

Once the skilled nursing facility signed up with Omnicare, there was very little communication between the pharmacy, the federal government, and the facility regarding Part D. In late September, 2005, there was a CMS teleconference that told the facilities to expect the yellow Medicare sheets listing which PDP in which they would be enrolled sometime in October, and that there would be over forty PDPs to select from for the general population and a limited number for the dually eligibles.

In early October I held both a family and resident council meeting, alerting both groups that although the facility had been given very limited information, to expect the Yellow Letter in the mail and make sure if they received it to give the nursing home facility. The non-dually eligibles were given preliminary information about the program and since it was optional, was told that they had a choice to enroll, prove otherwise creditable coverage, or opt out of the program with the possibility of incurring the penalty after the open enrollment period expired.

During this period, the families and residents were confused as to why they, as dually eligible residents, were being auto-enrolled into a pharmacy plan that our LTCP might not be contracted with and why they could be assigned into a PDP that did not have their medications. The anxiety was very high, as people became very concerned with what would happen if they did not receive their medications and what would be the system if they were denied access.

CMS at this point was not releasing any definite information. I had daily contact with Omnicare and Medicare, yet neither could give me any answers.

Concurrently, while trying to allay the families' and residents' worst fears, I was having weekly meetings with members of our medical and nursing administration, social services, and resident finance departments in an effort to prepare for the deluge of paperwork that I was assured would be coming. The staff was primarily concerned with what would happen if a PDP denied the resident's medication, since under 42 C.F.R. § 483.60, a nursing facility is charged with providing all medications and biologicals, and non-compliance could not only lead to liability, but would surely jeopardize the residents' health and welfare.

I was assured by Omnicare that we could set up a system whereby the prescription medications would always be delivered, as long as the facility would guarantee payment even if the PDP declined to pay, which I accepted. I felt worse than a man with a gun at his head -- it felt more like a Howitzer. I could not risk a resident not receiving their medication, however, with the thought of already losing over half a million dollars in Medicaid revenue, I would be assuming the risk of ordering over eighteen hundred medications, equivalent to an average of nine medications per dually eligible resident, and possibly not being paid. This could represent close to one hundred thousand dollars per month plus liability for non-compliance, if the facility did not efficiently implement the program. I was fairly certain that this was *not* something that was going to look good on any future resumes.

The residents did receive the Yellow Letters beginning in early November, however they were addressed to the residents themselves, which posed a problem as more than 80% of this skilled nursing facilities' population is not able to comprehend even rudimentary information and the nursing facility cannot legally open their mail without the designated representative's

approval. CMS did allow the administrator to send out a letter to the responsible parties granting a skilled nursing facility designee the right to open the mail for this purpose, which we did.

B. The Enrollment Process Begins.

In mid-November, 2005, the Medicare website posted the previously-described formulary finder tool which allowed Medicare beneficiaries access to change their PDP designation or enroll in a Part D plan if not already enrolled. While the website was user friendly enough to someone with, say, a degree in software development, most of the residents did not have Internet access in the first place, nor did they have any information about the individual PDPs or a guarantee that any PDP they might select would have a contract in place with the facility's long-term care pharmacy. CMS sent a formal communication to the Administrators of individual facilities outlining the facilities' responsibility to the Medicare beneficiaries, which included: assistance with enrollment, an extended transition period, writing policies and procedures, educating the necessary staff members about the plans, and ensuring that the exceptions and appeals process was seamless. An easy enough letter to put together, since CNS was not the one charged with doing the work.

There was a great deal of confusion with the enrollment process and the skilled nursing facilities were further constrained by the marketing provision of the Part D law, which did not allow a facility to endorse a particular PDP, even if it was suitable for the beneficiary. The facility was simply supposed to meet with each Medicare beneficiary or their authorized representative, defined in the federal regulation as an individual legally charged to act on behalf of the resident, and input into the formulary finder the current medications and any possible future medications. This was obviously a huge administrative burden, as there were quite a few residents that did not even *have* such a representative, and it was difficult and time consuming to

explain it to those residents and representatives who were both available and capable of understanding something this complex. In response to an outcry from long-term care advocates who feared that a resident who was auto-enrolled into a plan that was not in their best interest would not have the ability to switch plans -- and pondering, no doubt, what that patient's class action counsel would soon be saying in Federal District Court -- in late November, 2005, CMS ruled that the residents in a nursing home would be able to change their PDP designation, for the foreseeable future, with 30 days' advance notice.

The enrollment for the non-dual eligibles was problematic because they were subject to co-pays, premiums, and they had over forty plans from which to choose. For this segment, like the community beneficiaries, Part D was actually voluntary, however, CMS mandated that the nursing facilities try to enroll as many participants before the May 15, 2006 initial enrollment period, after which the beneficiary would incur a 1% per month penalty for non-enrollment without creditable coverage or be ineligible to sign up until the next the enrollment period. Many of the non-dual eligibles had difficulty understanding the limitations of the plan, including the deductibles, being subjected to the donut hole, and the monthly premium.

C. The Transition Period.

Skilled nursing facilities were granted a 90-day transition period as a result of the hue and cry of the long term care advocates as previously described. During this period, all of the residents would continue receiving their medications as prescribed and not be subject to the PDP's exceptions or appeals process. This period from January 1, 2006 to March 31, 2006 enabled the skilled nursing facility to adjust to the process, and to see and evaluate the pitfalls of the program. During this time, there were approximately fifteen instances in which residents did

not receive a medication, even though the facility had been assured by Omnicare and CMS that during the transition period there would be no denials.

D. The Exceptions and Appeals Process.

Even though the skilled nursing facilities were aware that there would be an appellate process of some sort within which to appeal disputes, it was not until late December, 2005 that CMS published suggestions about the process. The prior authorization/exception process is when a non-formulary drug is requested and there is not a formulary drug that will be as effective. In order to obtain an exception, the physician must justify why the medication is medically necessary and supply supporting documentation. It is when the exception is denied that the appeals process begins.

Development of this process has been the most difficult for the facility as there was no guidance as to process and policy development. Since each PDP has an individual formulary and there are over forty possible formularies that to which any one of the present and potential residents could be assigned, it was up to the facility to develop a formulary system that the prescribing physicians could access to see if what they were prescribing was actually on the formulary or would require an exception. The list took several days to compile and then was placed on each unit via hardcopy and computerized version. In late January, 2006, CMS gave all of the physicians and facilities access to www.epocrates.com, which is an online prescribing formulary locator.

The next system that needed to be formulated was a way to oversee the prior authorization/exceptions and appeals process. I was able to work with Omnicare and the medical staff to coordinate a fax system. When a medication is prescribed that is not contained in a current PDP formulary, the PDP electronically lets Omnicare know. Through an intermediary,

Omnicare sends the facility a fax that alerts the facility that a medication has been prescribed off formulary and the corresponding formulary drug associated. The prescribing physician can either choose to simply check off the formulary equivalent and fax it back or select the option of filing an exception with the PDP, which requires medical justification and at times back up medical records. The system has been streamlined so that the turnaround time for the physicians is 48 hours and Omnicare automatically sends a three-day supply of the drug regardless, so that the resident always has the correct medication as ordered and will bill the facility if the order is changed.

E. Potential Liability From Barriers to Prescription Access.

Because it is the skilled nursing facility that is charged with supplying the prescription medications, Medicare Part D is exposing the facilities to possible liability if the non-covered drugs are not accessible to the beneficiaries. With the emplacement of several barriers to access to medication, e.g., prior authorization, step therapy, volume limits, exceptions, and appeals, there are many opportunities for a resident to not receive his or her medication. The only certain way to assure that this does not occur is to expose the skilled nursing facility to the significant financial burden of covering the medications when and if the PDP does not cover the medication or in the event that the physician does not respond in a timely manner.

VI

CONCLUSION

Although still well into its infancy, Medicare Part D has proven to be a challenging undertaking for the skilled nursing facility sector. Touted as providing greater consumer choices and more extensive access to prescription medications, it has not lived up to either goal. Instead

it has become an enormous administrative burden and potential liability for nursing home operators, and has created real barriers to access to medications for some of our most vulnerable elderly citizens.