

# Chapter 24 Medicare Part D Benefit

## Medicare Part D Benefit

### Medicare Part D Benefit

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This chapter focuses on the intricacies of Medicare Part D prescription drug coverage, with particular emphasis on how the rules apply to group health plans. Other aspects of Medicare are covered in chapter 10. Other prescription drug benefits are discussed in chapter 16.

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## Introduction

### Q 24:1 What is the Medicare Modernization Act (MMA)?

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. No. 108-173) was signed into law on December 8, 2003. It created a new Medicare Part D, which established a voluntary outpatient prescription drug benefit for seniors and qualified disabled persons. Prior to Part D, there was an interim drug discount card program that started on June 1, 2004, and ended on May 15, 2006. The full prescription drug benefit began on January 1, 2006.

A part of the Medicare administration has been completely delegated to the private sector. Part D plans include:

- Prescription drug plans (PDPs)—private, stand-alone plans that offer drug-only coverage
- Medicare Advantage plans (MA-PD plans)—plans that offer both prescription drug and health coverage. These plans exist in every state except Alaska and Vermont.

### Q 24:2 How are PDPs and MA-PDs established?

PDPs and MA-PDs are established in geographical regions of the United States. Regions are established based on the following key factors:

- Eligibility of the population and the capacity of health care systems for service delivery
- Beneficiary considerations

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- Limited variation in prescription drug spending

Using these criteria, the Centers for Medicare & Medicaid Services (CMS) established 34 PDP and 26 MA-PD regions across the country.

### Q 24:3 What are the general requirements of the Part D prescription drug plans?

The PDPs and MA-PDs:

- Must offer a basic drug benefit called the “standard benefit,”
- May offer supplemental benefits called “enhanced benefits,”
- Can be flexible in benefit design, and
- Must follow marketing guidelines.

### Q 24:4 How does the new Medicare Part D integrate with Medicare?

Medicare has four components:

- Part A—covers inpatient care (e.g., hospital, skilled nursing facility care, home health care, hospice)
- Part B—covers outpatient care (e.g., medical visits, durable medical equipment [DME], a few prescription drugs)
- Part C—covers managed care (enacted as Medicare+Choice in 1997 and now known as Medicare Advantage)
- Part D—covers voluntary prescription drug benefit

### Q 24:5 What is the estimated impact of Part D on the U.S. population?

From the vantage point of drug plans, the Medicare population is the last large growth segment. It is estimated that the Medicare and Medicaid populations consist of:

- 43 million eligible Medicare beneficiaries
- Approximately 14 million who may qualify for limited income assistance
- About 6 million beneficiaries who will move automatically from Medicaid to Medicare

### Q 24:6 What are the Part D cost projections for 2008?

In January 2008, the Congressional Budget Office (CBO) projected that Part D will cost \$45 billion this year, down from its 2007 projection of \$49 billion. According to the CBO estimate, the cost of PDPs is only approximately 2 percent higher than for 2007. However, because Part D will recover savings from previous years, the costs for 2008 will be less than that for 2007.

### Q 24:7 What were the Part D cost projections for 2007?

Premiums for Medicare drug plans increased 13 percent over 2006, when the drug plans went into effect. According to House Oversight and Government Reform investigators, prices for 10 of the most prescribed brand name medications increased an average of 6.8 percent for the first quarter of 2007, while

wholesale prices for the same drugs rose just 3 percent. The investigators cite atorvastatin (Lipitor®) as an example. The cost of one month's supply climbed 9.6 percent to \$84.27 in mid-April 2007, from \$76.91 in mid-December 2006. Over the same period list prices climbed 5 percent. Rebates were predicted to be a cost offset by Medicare actuaries who expected insurers in 2007 to secure manufacturers' rebates of 6 percent, and then pass those savings on to seniors and the government. However, drug manufacturer rebates to insurance companies are expected to total 4.6 percent of total drug costs in 2007, which is down from 5.2 percent in 2006.

### Q 24:8 Which beneficiaries benefit the most from Part D?

Certain beneficiaries will have the greatest benefit from Part D. The beneficiaries benefiting the most from Part D are:

- Patients with no current drug insurance,
- Patients who qualify for limited income assistance,
- Patients in Medicare Advantage plans with no drug coverage, and
- Patients who spend more than \$800 per year on prescription drugs.

### Q 24:9 What beneficiary communications are available from CMS for information on Part D?

CMS provides the following communications to educate beneficiaries about Part D:

- Medicare & You 2008—pamphlet that contains health plan benefit and cost information
- <http://www.medicare.gov>—price comparison Web site that allows beneficiaries to compare prices, fees, and other drug plan features
- 1-800-MEDICARE—call center that provides program information

### Q 24:10 What other resources are available to health care practitioners, payers, and other interested parties?

Pharmacists are a major source of information for patients. For example, they were a primary avenue used by seniors to sign up for the Medicare discount card program. A study from the Kaiser Family Foundation found that one-third of senior beneficiaries will likely turn to their pharmacist for advice about the Medicare drug program. As a result, additional services are available for pharmacists and other health care professionals from the following sites:

- <http://www.medicareresourcecenter.com>
- <http://www.ncpanet.org>

## Enrollment

### Q 24:11 Who is eligible for Part D?

Each individual entitled to Medicare Part A or enrolled in Part B qualifies for Part D coverage. Individuals enrolled in traditional Medicare will receive their benefits through a stand-alone PDP. Individuals enrolled in a Medicare Advantage plan will have coverage through an MA-PD plan.

Most eligible Part D beneficiaries were able to choose a Part D plan starting on November 15, 2005. Two special groups were identified for consideration:

- Dual eligibles (individuals eligible for both Medicaid and Medicare). These individuals were automatically enrolled in a Part D plan.
- Limited income beneficiaries. These individuals were eligible for a limited income subsidy.

## Q 24:12 Who are dual eligibles?

A dual eligible is a Medicare beneficiary who is currently receiving state Medicaid benefits. Medicaid drug coverage for Medicare eligibles was terminated on December 31, 2005. In order to continue drug coverage, dual eligibles were automatically assigned to qualifying plans starting in October 2005. These individuals can switch out of their automatically assigned plans every 30 days.

## Q 24:13 When does the drug subsidy for dual eligible seniors start?

The Medicare Part D subsidy starts on the date when the dual eligible senior becomes eligible. If a delay occurs in starting the senior on the program, the senior is eligible for retroactive coverage for prescription medications back to the eligibility date.

## Q 24:14 What is *creditable coverage*?

Some patients will not have to pay a late enrollment penalty if they are currently receiving retiree coverage that is at least as good as Medicare Part D. This current coverage is “creditable.” The retiree benefits coordinator for their employer is the contact person for determining whether their coverage is creditable.

Creditable coverage notices must be sent annually and at other times specified by Medicare. These notices are commonly sent when an active worker first becomes eligible for Medicare or when the employer group coverage changes. Most employers send creditable coverage notices with annual open enrollment materials sent to all active workers and retirees. COBRA notices have no applicability to the Part D program.

CMS has issued guidance on the content, model language, and timing of creditable coverage notices that must be provided to Part D-eligible Medicare beneficiaries.

## Q 24:15 Who are limited income beneficiaries?

Potential low-income individuals can apply for eligibility determination through mailings to potential eligibles, applications in pharmacies, Internet applications, walk-ins to state Medicaid offices, or walk-ins to Social Security Administration (SSA) field offices. After eligibility is determined the applicant is notified of the determination.

These individuals had a two-step enrollment process. First, they were pre-screened for income and assets through an application process administered by SSA. After approval from SSA, the beneficiary had to choose a Part D plan after November 15, 2005. If the limited income beneficiary did not choose a Part D plan by May 15, 2006, he or she was automatically enrolled into a qualifying Part D plan. (*Note: Dual eligibles did not have to fill out SSA applications.*)

## Q 24:16 What are the enrollment options for beneficiaries?

The first-year open enrollment period was November 15, 2005, through May 15, 2006. Beneficiaries have an option of at least two Part D plans per region. The regions are defined by CMS and include 34 PDP and 26 MA-PD regions.

## Q 24:17 What is the annual coordinated election period (AEP)?

The AEP is the open enrollment period each year. This period is defined as November 15 to December 31 of each year.

## Q 24:18 Can a retiree leave the employer's coverage at any time during the year and join another plan?

Retirees must follow their employers' plan coverage rules to remain eligible for their retiree coverage. However, if retirees decide to leave their employer coverage midyear, they may enroll in a Medicare Part D plan only during the Medicare open enrollment period. For example, if a retiree left the employer's Part D plan in July, he or she would have to wait until the November open enrollment period for coverage for the following year.

Exceptions are allowed for the following special circumstances:

- Beneficiaries who permanently move out of the plan service area
- Individuals entering, residing in, or leaving a long-term care facility
- Involuntary loss, reduction, or non-notification of creditable coverage
- Other exceptional circumstances

## Q 24:19 What is the late enrollment penalty?

Some Medicare patients may be subject to a late enrollment penalty if they do not sign up for Part D when they are first eligible. This late penalty fee is a carryover from Medicare Part B. Two categories of patients are at risk. The first group includes patients who were eligible for Medicare before January 2006 and had to sign up by May 15, 2006, to avoid a higher premium. The second group includes patients who became eligible for Medicare after January 2006 and must sign up for Part D within 63 days after the end of their initial enrollment period to avoid a higher premium.

The higher premium will be based on an increase of at least 1 percent of the base premium (i.e., \$27.93 for 2008) per month for every month that they waited to enroll. This premium may change each year. For example, in 2008 the rate was 28 cents per month. So, if the beneficiary waited six months to enroll, they would pay \$1.68 per month in addition to his or her base premium.

The fees will be reflected in higher monthly premiums for the **beneficiary's lifetime**. However, if a Medicare beneficiary has a creditable coverage equivalent to or better than Part D (e.g., employer or retirement plan), this penalty does not apply.

## Employer Incentives to Participate

### Q 24:20 What has been the experience of companies regarding prescription drug benefits for retirees over the past two decades?

Generally, companies have not provided prescription drug benefits to retirees because of the high cost of drugs and the costs of health care overall. According to Leslie Norwalk, CMS deputy administrator, "If you look at large employers back in 1988, about 66 percent offered drug benefits to retirees. By 2002, that percentage had dropped to 37 percent, and we feel it has continued to fall since."

## Q 24:21 What has CMS done to encourage companies to provide retiree prescription benefits?

Leslie Norwalk, CMS deputy administrator, explains the CMS position as follows:

In this era of corporate austerity companies that think about where they can cut costs to be competitive are choosing to cut retiree benefits, depending on their union contracts. But under Part D, there is a major financial incentive to reconsider. We're saying to them, "Stay in the game, and we'll write you a check that could be worth hundreds of thousands of dollars." Clearly, a major reason why an employer or union may want to do this is because it won't have to pay the entire premium. In other words, for those that don't offer drug benefits, now may be the time to rethink.

## Q 24:22 What are the options for companies to incorporate Medicare Part D into their existing benefits?

Three basic options are available to companies that elect to incorporate Medicare Part D into their existing benefits:

1. *Retiree Drug Subsidy*: The employer can accept a plan-sponsor subsidy averaging \$668 per year per retiree (actuarially derived). In effect, the plan sponsor offers their benefit plan as a substitute for Part D. Under this option, the plan sponsor receives a check from the government that represents 28 percent of annual prescription drug spending (ingredient cost plus dispensing fee only) between \$250 and \$5,000 per retiree—this is the \$668 per-retiree-per-year. In order to be eligible for the subsidy, the company must pass an actuarial equivalence test. This actuarial attestation test means that deductibles, coinsurance, and cost-sharing are as good as those found in the Medicare plan.
2. *PDP or MA-PDP*: The employer can contract with CMS to become an official Prescription Drug Plan (PDP) under Medicare and offer the Part D benefit to retirees themselves. Alternatively, the employer can hire or outsource to an outside PDP or Medicare Advantage plan to serve as its employer-specific plan. Many health insurers (e.g., Aetna, Blue Cross/Blue Shield, Cigna, Highmark Blue Shield, Humana, PacifiCare/United Health), pharmacy benefit managers (PBMs) (e.g., CVS/Caremark, Medco, Express Scripts, Ovation/Walgreens, Universal American Financial Corp./CVS), and coalitions like the Community Care Rx are offering outsourcing services for companies. Other coalitions include National Community Pharmacist Association, Computer Sciences Corp., and Member Health.
3. *Wraparound plan*: The employer can offer a separate benefits plan that "wraps around" Medicare Part D. Under this option, the employer fills in retiree drug-benefit voids that are not covered under Part D. Historically, the company or union can offer a supplemental plan in which Medicare pays typically 80 percent of the cost of a service and the company pays a portion—or all—of the remainder. Under Part D, the company can pay the cost of the deductible in a supplemental plan, or a percentage of the coverage gap (or "donut hole"), or, for example, 25 percent of total out-of-pocket costs.

## Q 24:23 What is the 28 percent retiree drug subsidy?

This is the first option above. Companies that decide to offer retiree drug programs under Part D will receive a tax-free subsidy from the federal government that is estimated to pay companies on average \$668 per retiree.

## Q 24:24 How does PBM “lock-in” or “spread” pricing impact companies that offer the drug subsidy?

On July 20, 2006, CMS stated its intent to issue a Notice of Proposed Rulemaking proposing that the “pass through” model will be the only acceptable methodology for calculating beneficiary cost-sharing and gross covered drug costs through the benefit, as well as reporting drug costs on explanations of benefits (EOBs) and prescription drug event (PDE) records. Due to the time required to issue the final rule, CMS delayed implementation until plan year 2008. For plan year 2008, as in 2006 and 2007, Part D sponsors that use a PBM may apply either the pass-through or lock-in pricing approach when calculating cost-sharing and reporting drug costs. To ensure transparency in bid development, all plans will be required to submit an actuarial attestation that identifies the methodology used in 2008 bid development. [<http://edocket.access.gpo.gov/2008/pdf/08-1244.pdf>]

## Q 24:25 What are some of the concerns for companies in choosing an option?

The first option is the drug subsidy. This option seems to be the easiest and potentially the most lucrative for a company. For example, actuaries estimate that for a company in a 25 percent tax bracket, the tax-free \$668 estimated subsidy works out to about \$890 per retiree. For those companies in the 35 percent tax bracket, the subsidy is estimated to result in \$1,035 per retiree per year.

The second option is Part D. The concern for this option is how much the company will actually pay for the services of the health plans and PBMs. Furthermore, it is expected that there will be a provider shake-out over time, such that some vendors may exit the market. Until the market stabilizes, this option is considered more risky.

The third option is a coordination-of-benefits concern. Companies believe that most pharmacies are not prepared to manage retiree patients with two benefits, nor do they have the technology to administer more than one benefit.

## Q 24:26 What are PDEs and how do they impact data requirements for CMS reporting?

Medicare Part D Prescription drug events (PDEs) are data from prescription claims that are reported to CMS by prescription drug plans (PDPs) and Medicare Advantage Plans (MA-PDs). The PDE data is used by CMS for reporting to Congress and the public on the overall statistics associated with the Medicare prescription drug benefit, reconciliation of payments by plan sponsors, evaluations of the program, making legislative proposals, and conducting demonstration projects.

The PDE dataflow was described in the CMS 2006 PDE Regional Training Participant Guide, September 2006. The dataflow is as follows:

- Pharmacy Provider
- TrOOP (true out-of-pocket) Cost Facilitator
- Plan
- PDE Record
- Prescription Drug Front-End System (PDFS)
- Drug Data Processing System (DDPS)
- Drug Benefit Calculator (DBC)
- Payment Reconciliation System (PRS)

Because plans are paid by CMS prospectively, this dataflow ensures that plans report all eligible beneficiaries, and data for payment reconciliation. Errors in submissions will result in underpayments to the plans or CMS claw backs of payments from the plans.

## Standard Benefit

### Q 24:27 What is the *standard benefit design*?

The *standard benefit design* entails a monthly premium of approximately \$37 that varies by PDP and MA-PD region. The annual deductible is \$275 in 2008, and is indexed annually. The primary coverage after the deductible requires the beneficiary to be responsible for approximately 25 percent of drug costs until he or she reaches \$2,510 in 2008 (vs. \$2,400 in 2007) in drug spending (not including his or her monthly premium).

### Q 24:28 What is the *coverage gap*?

After spending \$2,510(not including monthly premiums) in 2008 (compared to \$2,400 in 2007), the beneficiary is responsible for 100 percent of drug costs until he or she reaches \$4,050 in 2008 (vs. \$3,850 in 2007) in true out-of-pocket costs. This responsibility corresponds to more than \$5,000 of total prescription drug spending (more if a person has a wraparound plan).

After \$5,726 of total prescription drug spending in 2008 (vs. \$5,451.25 in 2007), the beneficiary receives catastrophic coverage. For this coverage the beneficiary is responsible for about 5 percent of drug costs after personally spending \$4,050 out-of-pocket costs.

### Q 24:29 What is the *low-income benefit design*?

For beneficiaries eligible for low-income assistance, there is a different benefit design. This design is summarized in the table below.

<i>Income</i>	<i>Premium / Deductible</i>	<i>Copayments (Cost Sharing)</i>	<i>Copayments For Catastrophic Coverage</i>
Most dual eligibles	\$0 / \$0	\$1 for generics / \$3 for other until \$5,100 in total drug spending	\$0
Below 135 percent of federal poverty level (FPL)	\$0 / \$0	\$2 for generics / \$5 for other until \$5,100 in total drug spending	\$0
Below 150 percent of FPL	Sliding scale premium / \$50	15 percent of drug costs from \$50 to \$5,100	\$2 for generics / \$5 for catastrophic coverage

## Q 24:30 What is the “True Out-of-Pocket” (TrOOP) cost to a patient?

The TrOOP cost is the beneficiary cost-sharing for Medicare Part D benefits before catastrophic coverage begins. Because several different payments contribute to TrOOP, CMS awarded a contract to NDC Health to provide coordination-of-benefits systems. NDC Health is responsible for systems that will monitor TrOOP on a pharmacy level so that beneficiaries can question their pharmacists about how close they are to catastrophic coverage. To ensure accuracy of this information, NDC Health is required to route claims for benefits paid by entities other than Medicare to the prescription drug plans (PDPs). This requirement ensures that what seniors pay at pharmacies takes into account the appropriate level of their Medicare coverage.

## Q 24:31 What is included in the TrOOP cost?

A beneficiary’s actual out-of-pocket costs are calculated according to the following formula, using 2008 amounts:

\$275	Deductible
\$558.75	25 percent of drug costs in the initial coverage (\$275 – \$2,510)
\$3,216.25	100 percent of drug costs in the donut hole (\$2,510 – \$5,726.25)
\$4,050	TrOOP costs

The following is an example:

<i>Actual Drug Cost</i>	<i>Medicare Pays</i>	<i>Beneficiary Pays</i>	<i>Total Paid</i>
\$0–\$275	\$0	\$275 (deductible)	\$275
\$275.01–\$2,510	\$1,676.25 (75%)	\$558.75 (25%)	\$833.75 = (\$275 + 558.75)
\$2,510.01–\$5,726.25	\$0 (coverage gap)	\$3,216.25	\$4050 = (\$833.75 + \$3,216.25)
\$5,726.26 +	About 95%	About 5%	Varies

## Q 24:32 What other payments may count toward TrOOP?

Beyond drug spending by the beneficiary, other payments can count toward TrOOP. These include payments from:

- Another individual (such as a family member or friend);
- A state pharmaceutical assistance program (SPAP);
- A charity; or
- A personal health savings vehicle such as a flexible spending account, health savings account, or medical savings account.

### Q 24:33 What beneficiary costs are not included in the TrOOP?

The following beneficiary costs are *not* included in the TrOOP:

- Monthly premiums (about \$37/month)
- Most third-party payment arrangements
- Drugs purchased outside of the United States
- OTC drugs
- Drugs not on the plan's formulary
- Drugs not covered by law

### Q 24:34 What beneficiary insurance programs are not included in the TrOOP?

The following sources of insurance payments are not applied to the TrOOP:

- Employer/retiree group health plans
- TRICARE
- Black lung
- Veteran's Administration (VA)
- Worker's compensation
- Automobile/no-fault/liability insurance
- Supplemental benefit portions of PDP or MA-PD

### Q 24:35 What entities provide competing or alternative insurance coverage?

There are other insurers for which benefits must be coordinated with Part D payments. These entities providing competing or alternative insurance coverage include:

- Employer Group Health Plan (EGHP)
- VA
- TRICARE
- Medicaid
- Medigap

### Q 24:36 What options will beneficiaries have regarding their Medigap insurance?

Medigap provides a unique problem. Enrollees with Medigap H, I, or J insurance must receive a creditable coverage notice. They also must be notified of their options. These options include that their Medigap insurance will not be sold, issued, or renewed after 2005; however, a policy may be renewed if it is modified to exclude drug coverage or if the person does not enroll in a Medicare prescription drug plan.

There are also two new Medigap plans—K and L.

Medigap Plan K includes coverage of 50 percent of the cost-sharing applicable under Medicare Parts A and B, except for the Part B deductible. Plan K can cover 100 percent of inpatient hospital coinsurance and 365 lifetime days of inpatient hospital services. Also, Plan K can provide for 100 percent of any cost sharing for preventive benefits. The annual out-of-pocket limit for this insurance was \$4,000 in 2006, and is indexed thereafter.

Medigap Plan L includes coverage of 75 percent of cost sharing applicable under Medicare Parts A and B except for the Part B deductible. Similar to Plan K, Plan L can cover 100 percent of inpatient hospital coinsurance and 365 lifetime days of inpatient hospital services. Also, Plan L can provide for 100 percent of any cost sharing for preventive benefits as in Plan K. The annual out-of-pocket limit for this insurance was \$2,000 in 2006, and is indexed thereafter.

## Q 24:37 How does Part D apply to U.S. territories?

Residents of Puerto Rico and other territories are not eligible for Part D subsidies. The territories may submit a plan to receive additional Medicaid funds to provide covered Part D drugs to low-income Part D-eligible individuals.

## Pharmacy Network Contracting

### Q 24:38 What are the elements of Medicare Part D pharmacy network contracting?

Part D pharmacy network contracts require specific expectations for the plan sponsors. Sponsors expect these plans to meet the following criteria:

- Work plans must be included in the application.
- Performance and service criteria must be included in pharmacy contracts.
- Contracts must contain any willing providers.
- Contracts must have convenient access requirements for patients who routinely receive benefits through the network.

### Q 24:39 How is the pharmacy network constructed?

Initially, Part D plans had to establish pharmacy networks by August 1, 2005. These networks must obey standards that can be no less than the TRICARE Retail Pharmacy access standards. These requirements are based on **state**—not PDP or MA-PD region. MMA contains an “any-willing provider” provision such that any pharmacy that wishes to participate in a Medicare plan can participate if they accept the standard terms and conditions of the participating pharmacy agreement. This requirement pertains only to initial networking and did not extend past August 1, 2005. After this time, health plans could close the pharmacy networks if they chose.

### Q 24:40 What are the retail pharmacy access standards?

The retail pharmacy access standards are based on the TRICARE standards on convenience and access to pharmacies. These standards are based on geography and type of pharmacy outlet. The geographical standards are as follows:

- Urban—90 percent of beneficiaries in the plan’s service area, on average, live within 2 miles of a retail pharmacy participating in the plan’s network

- Suburban—90 percent of beneficiaries live within 5 miles of a retail pharmacy
- Rural—70 percent of beneficiaries live within 15 miles of a retail pharmacy
- Only retail pharmacy outlets count toward TRICARE standards except:
- Indian Health Service, Tribes, or Urban Indian program (I/T/U) pharmacies
- Federally qualified health center pharmacies
- Rural health center pharmacies

### Q 24:41 What is the “level playing field” requirement?

There is a so-called level playing field requirement that no mandatory mail order is allowed. In addition, PDP sponsors may not include only mail order pharmacies in their network. This requirement is not completely exclusive. For example, if retail pharmacies refuse the 90-day option, then a PDP can still offer a 90-day mail option. Adequate retail emergency access for enrollees is also necessary. However, the patient is responsible for any higher cost-sharing that applies at a retail pharmacy; for example, the patient may pay the normal copay plus the difference between the mail and retail 90-day rates. The implications of this requirement are as follows:

- If a Part D plan offers a 90-day supply at mail, then it must offer a 90-day supply option at retail.
- The plan is not required to offer a 90-day supply option at retail if it does not have a 90-day mail option.

### Q 24:42 What are the benefits of preferred pharmacies?

Plans can offer benefits with preferred pharmacies. These discounts apply to standard benefits but not to dual eligible or low-income beneficiaries. Plans with preferred pharmacies can provide lower reimbursement to participating pharmacies and, in turn, provide more advantageous copays and co-insurances to beneficiaries. However, plans must maintain actuarial equivalence of 25 percent patient responsibility, meaning that the preferred pharmacy benefits still must obey the standard benefit package.

### Q 24:43 What are the “out-of-network” access requirements?

Plans must ensure adequate access to out-of-network pharmacies when the patient cannot reasonably be expected to obtain that drug at a network pharmacy. However, the patient must not access an out-of-network pharmacy on a routine basis.

### Q 24:44 Are there mandated pharmacy reimbursements?

Congress did not set a minimum or maximum requirement for pharmacy reimbursement rates. The plan—that is, the market—determines reimbursement based on its network contracting.

Dispensing fees do have some limitations. They are limited only to those costs associated with the transfer and possession of a drug. These costs include checking for coverage information, performing quality assurance (QA) activities as mandated by the state, filling the container and providing to the customer, delivery at the point of sale, and overhead. Also, dispensing fees do not include any activities beyond the point of sale (e.g., pharmacy follow-up telephone calls or medication therapy management).

## Formularies and Part D

### Q 24:45 What are the requirements for formularies for Part D?

Formularies are encouraged for PDP and MA-PD plans. While each plan may develop its own formulary, there are several rules governing the design of these formularies. CMS contracted with the United States Pharmacopoeia (USP) to develop formulary guidelines. USP identified 146 therapeutic categories that must be included in all Part D formularies. In addition, if a generic is available, it must be included in the formulary. Also, if preferred drugs are defined, the rebates collected must go to the payer to decrease the cost of the program.

Part D formularies must also comply with the following requirements:

- They must include at least two drugs in each therapeutic category and class of covered Part D drugs.
- They may, and likely will, include prior authorizations, step therapy, generic drug requirements, and preferred brand drugs.
- They must include all or substantially all drugs in the following classes: antidepressants, antipsychotics, anticonvulsants, anticancer, immunosuppressants, and HIV/AIDS medications.

### Q 24:46 What is the formulary key drug types (FKDTs) mandated for Part D formularies?

CMS originally developed criteria for approval of Part D formularies. Included in the CMS criteria was the mandate for one drug from each therapeutic category, as defined by USP, to be required in any Part D formulary. These so-called “key drug types” or FKDTs expanded the Part D formularies and caused controversy over inclusion of drugs regardless of information on effectiveness and safety. In the 2008 CMS Call Letter, the mandate criteria are removed. Essentially, CMS modified their prior mandate and removed the FKDT criteria. The new formulary guidelines indicate that FKDTs must be considered as part of the “outlier” test for formulary review.

### Q 24:47 What are the requirements for dispensing generic drugs?

If the pharmacy dispenses a brand drug, they must inform the Part D patient of any differential between the price of the brand drug and the price of the lowest priced generic version of that drug available at that pharmacy. This disclosure is mandatory, and plans will ensure compliance with this provision on the retail level.

### Q 24:48 What medications are excluded from Part D?

Part D does not cover all medications. The general rule for coverage is that Medicare Part A or Part B pays first, and Part D kicks in only for medications that the other Medicare plans do not cover. The specific categories of medications that are not covered under Part D are as follows:

- Part A covered drugs
- Part B covered drugs
- DME supply drugs
- Immunosuppressant drugs received for a Medicare covered organ transplant

- Hemophilia clotting factors
- Some oral anti-emetic drugs
- Pneumococcal, Hepatitis B, and Influenza vaccines
- Antigens (e.g., allergy shots)
- Erythropoietin for treatment of anemia for patients in end-stage renal disease (ESRD) on dialysis
- Parenteral nutrition
- Intravenous immune globulin (IVIG)
- Benzodiazepines (e.g., Valium, Ativan, Xanax)
- OTC medications (e.g., medications for constipation, heartburn, pain)
- Cough and cold medications
- Prescription vitamins and mineral products (except prenatal vitamins and fluoride preparations)
- Medications for anorexia, weight loss, or weight gain
- Barbiturates (e.g., Phenobarbital)
- Fertility promotion medications
- Medications promoting hair growth
- Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale

### Q 24:49 What are DESI drugs and are they included or excluded from Part D formularies?

Drug Efficacy Study Implementation (DESI) drugs are excluded from Part D formularies. These are drugs that were approved solely on the basis of their safety prior to 1962. Thereafter, Congress required drugs to be shown to be effective as well. FDA initiated DESI to evaluate the effectiveness of those drugs that had been previously approved on safety grounds alone. These drugs, and those identical, related, and similar to them, may continue to be marketed until the administrative proceedings evaluating their effectiveness have been concluded, at which point continued marketing is only permitted if an NDA is approved for such drugs. The vast majority of the DESI proceedings have been concluded, but a few are still pending. [[http://www.fda.gov/cder/compliance/CPG\\_QandA.htm](http://www.fda.gov/cder/compliance/CPG_QandA.htm)]

### Q 24:50 Are vaccines included in Part D?

Yes. The Tax Relief and Health Care Act of 2006 (TRHCA) modified the definition of a Part D drug to include “for vaccines administered on or after January 1, 2008.” CMS released detailed operational guidance related to administration fees for Part D vaccines in 2008. In this guidance, CMS has interpreted this requirement to mean that the Part D vaccine administration costs are a component of the negotiated price for a Part D-covered vaccine, including the vaccine ingredient cost, a dispensing fee (if applicable), and a vaccine administration fee. Further, CMS has stated that Part D vaccines, including the associated administration costs, should be billed on one claim for both in- and out-of-network situations. As a result, if an in-network pharmacy dispenses and administers the vaccine in accordance with state law, the pharmacy would process a single claim to the Part D sponsor and collect from the enrollee any applicable cost sharing on the vaccine and its administration. Alternatively, if a vaccine is administered out-of-network in a physician’s office, the physician would bill the beneficiary for the entire charge. The beneficiary would, in turn, submit a paper claim to the Part D sponsor for reimbursement for the total charge: both the vaccine ingredient cost and the administration fee.

If a Part D vaccine has specific storage conditions that would limit physicians’ offices from

maintaining an inventory for their patients and the physician has a pharmacy dispense and delivers the vaccine for administration, the pharmacy would submit the vaccine ingredient cost and dispensing fee to the Part D sponsor for reimbursement and the physician would charge the beneficiary for the administration. CMS has said that pharmacy delivery services would be covered through contracted reimbursements with Part D plans.

### Q 24:51 *What are tiered formularies?*

Part D allows for preferred drug levels defined by formulary tiers. The first tier (tier 1) is the lowest level of cost sharing for the beneficiary. Subsequent tiers have higher cost sharing in ascending order. CMS reviews all plan formulary submissions to identify drug categories that may discourage enrollment of certain beneficiaries with Medicare by placing drugs in nonpreferred tiers. These plans must have exception procedures for these tiered formularies. The overall appeals process has five levels:

1. Redetermination by the plan sponsor
2. Reconsideration by an independent review entity
3. Review by an administrative law judge
4. Review by the Medicare Appeals Council
5. Review by a Federal District Court

## Medication Therapy Management (MTM)

### Q 24:52 *What are the requirements for an MTM program?*

The MMA states that a Part D plan must have an established MTM program. The program must have the following components:

- It is designed to ensure that covered Part D drugs that are prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use.
- It is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries.
- It may be furnished by a pharmacist or other qualified provider *and* may distinguish between services in ambulatory and institutional settings.

### Q 24:53 *What are the eligibility requirements for MTM services?*

MTM services target beneficiaries based on *all* of the following criteria:

- Multiple chronic diseases
- Multiple covered Part D medications
- Likelihood of incurring annual costs exceeding \$4,000 for covered part D drugs

### Q 24:54 *What are some examples of services provided under MTM?*

The following services may be included under MTM:

- Patient health status assessments

- Medication “brown bag” reviews
- Formulating, monitoring, and adjusting prescription drug treatment plans
- Patient education and training
- Collaborative drug therapy management
- Special packaging
- Refill reminders

Other services also may be included. In order to initiate any of the above services for a patient, pharmacies will receive e-mail messages from their plans to provide MTM for specific eligible patients.

## Q 24:55 How will pharmacists be paid for MTM?

Medicare Part D allows pharmacists to bill for MTM services. These services are to be paid through the medical benefit using Current Procedural Terminology (CPT) codes. Three CPT codes have been defined for these services; namely,

- 99605 (Replaces 0115T)—Initial face-to-face assessment or intervention with the patient; 1 to 15 minutes
- 99606 (Replaces 0124T)—Subsequent face-to-face assessment of intervention with the patient; 1 to 15 minutes
- 99607 (Replaces 0117T)—Each additional 15 minutes spent face-to-face with the patient; used in addition to 99605 or 99606

The above codes apply only to pharmacist services. Other codes must be used if physicians provide MTM. These codes are applicable to the MTM services for some Medicare Part D beneficiaries, but they also have been designed to be applicable to any payer type or practice setting.

## Skilled Nursing Facility (SNF)/Nursing Facility (NF) Impact

### Q 24:56 What is the population affected by Part D?

Nearly 3 million of the 40 million Medicare beneficiaries will reside in long-term care (LTC) facilities for some period of time in any given year. The patient profile for these beneficiaries is as follows:

- Age is 75 years and older
- Gender is 70 percent female
- Many suffer from cognitive disorders
- Most require assistance with activities of daily living
- Medication utilization is approximately 9 to 10 medications at any given time

There are approximately 1.6 million Medicare/Medicaid-certified SNF/NFs, with even more assisted living facilities.

### Q 24:57 What is the economic situation of LTC residents?

Nearly 70 percent of NF residents are dually eligible for Medicare and Medicaid benefits. Medicaid continues to have responsibility for daily care needs of the residents. Part D covers their prescription costs.

Residents of assisted living facilities are often wealthier at first, but then spend down to Medicaid eligibility. Some state Medicaid programs cover care in assisted living facilities through waiver programs. Some residents are eligible for low-income subsidies, but Medicare Part D can present a challenge due to assets testing.

### Q 24:58 **What is LTC pharmacy?**

*LTC pharmacies* are specialty pharmacies that provide medication dispensing and consulting services to residents of LTC facilities. CMS recognizes some of these facilities, but not all, for additional pharmacy services and dispensing fees under Part D. The following is a list of facilities providing LTC pharmacy services:

- Medicare and Medicaid certified SNF/NF skilled nursing facilities (recognized by CMS for Part D)
- Immediate care facilities for the mentally retarded (recognized by CMS for Part D)
- Assisted living facilities
- Board and care homes
- Prisons, jails, and hospice settings

### Q 24:59 **Who are the LTC pharmacy providers?**

Approximately 60 percent of the market is serviced by three publicly traded companies: Omnicare, Inc., PharMerica, and Kindred Pharmacy Services. The remainder of the market is serviced by independent LTC pharmacies.

### Q 24:60 **What was the situation for LTC pharmacies before Part D?**

Before Medicare Part D went into effect, LTC pharmacies received the most reimbursement from individual state Medicaid programs for NFs. The LTC pharmacies managed and developed formularies. There was little or no managed care intervention. Assisted-living residents primarily paid out-of-pocket for medications.

### Q 24:61 **How do LTC pharmacies operate under Part D?**

LTC pharmacies must enter into network agreements with PDPs. The PDPs manage formularies. Medicaid involvement is limited to payment for Part D–excluded drugs and for coverage gaps during transition.

There is still coverage under Medicare Part A. This coverage applies to beneficiaries admitted to NFs after a three-day hospital stay with skilled facility needs. Approximately 10 to 15 percent of beneficiaries are covered by the Medicare Part A SNF benefit. The Part A benefit is unchanged in 2008, such that the pharmacy bills the SNF for drugs and the facility bills Medicare directly.

### Q 24:62 **What are the access requirements for LTC pharmacies?**

In order to comply with Part D, plans must:

- Offer standard contracting terms and conditions to all LTC pharmacies (classified by CMS) in service areas;
- Contract with any willing LTC pharmacy; and

- Ensure convenient access to LTC pharmacies.

## Q 24:63 What are the services required of an LTC pharmacy under Part D?

A Part D plan may require that an LTC pharmacy must offer the following services:

- Drug packaging (including specialty packaging like bubble packs), labeling, and delivery systems for LTC medication use
- Pharmacy operations and prescription ordering
- Drug delivery service on a routine, timely basis (including emergencies around the clock)
- Access to urgent medications on an emergency basis
- Pharmacist on-call services (around the clock)
- Emergency boxes and log systems
- Standard ordering systems and medication inventories
- Drug disposition systems for controlled and non-controlled drugs
- Ability to provide IV medications
- Compounding/alternative forms of drug composition
- Miscellaneous reports, forms, and prescription ordering supplies (such as medication administration records [MARs])

It is important to note that these requirements reflect the services commonly provided in LTC. These services must comply with standards based upon best practices developed by the LTC industry and standards of compliance with federal and state nursing home, pharmacy, and other pertinent regulators. However, pharmacies may negotiate with PDPs for additional reimbursement for services.

The above services apply to the LTC setting only and not to assisted-living facilities not licensed as NFs. Also, these services do not apply to other state-licensed NFs that are not required to meet federal Medicare/Medicaid conditions of participation.

## Q 24:64 What pharmacy services are allowed for in payment of additional dispensing fees under Part D?

Additional dispensing fees are allowed and account for additional packaging and delivery services associated with providing medications to residents of NFs. Medicare Part D excludes payment for consultant pharmacies' monthly drug utilization regimen review (DUR). DUR remains the responsibility of the NF under Medicaid as part of the contract with the LTC pharmacy.

## Q 24:65 What is the CMS guidance on coverage of infusion/inhalation therapy in NFs under Part D?

First, the LTC facility must be used as the location code for inhalation. Second, CMS has indicated that infused medications that are not administered by a physician are covered by Part D, and not Part B, in a nursing facility. The physician should include information on the prescription that administration is to be in an NF. The LTC pharmacy will then dispense the medication and will be paid a dispensing fee but will not be paid for additional services. In addition, the payment for infusion therapy will not include services unless the provider uses Medicaid Federal Financial Participation. In such cases there is no payment for dispensing, but there is payment for services and supplies.

## Q 24:66 What are the other requirements for participation for LTC beneficiaries under Part D?

Certain requirements are unique to LTC pharmacies. The requirements are:

- A special enrollment period for admission or discharge in NFs.
- No copay for dual eligibles in NFs.
- Special appeals and exceptions processes.
- Formulary transition requirements for movement of patients from NF to PDP formularies.

Ultimately, the NF is responsible for all aspects of care for residents, including drugs. If Part D does not cover drug therapy, then the facility is responsible, not the LTC pharmacy.

## Q 24:67 What are the key issues for LTC pharmacies under Part D?

Several areas of compliance are specific to LTC pharmacies, including the following:

- Enrollment issues
- Formularies and drug coverage
- Coordination of benefits (COB) and service location
- Exceptions and appeals

## Q 24:68 What are the enrollment issues for LTC under Part D?

Enrollment provides particular challenges in LTC owing to the uniqueness of the population. These issues include the following:

- Enrollment information is often incomplete and contains key errors in notification among Medicare, Medicaid, LTC pharmacies, and the NFs.
- Claims processing is not the same as in ambulatory care because of the daily administration of medications.
- Many dual eligibles are not listed as Medicaid eligible.

## Q 24:69 What are the formulary issues in LTC under Part D?

The application of managed care and PDPs to LTC provides several challenges, including the following:

- It is necessary to determine how the formulary transition process is managed.
- Patients are permitted 31-day supplies under Medicaid, but PDP plans may not allow for different day supply limits.
- Utilization management tools are mandated under LTC standards, which may differ from PDP tools, leading to application and billing problems.
- The exception and appeals processes are different in LTC from ambulatory plans. For example, the “expedited” process in LTC requires a more immediate response than is common in ambulatory care.
- It is necessary to determine how excluded drugs are to be managed.

## Q 24:70 What are the coordination-of-benefits/service location issues in LTC under Part D?

COB is a major issue for NFs because of the difference in policies for payment for infusion and inhalation medications as opposed to the usual oral medications used in ambulatory care. The difference in payment policies is due to the lack of coordination of Medicare/Medicaid and PDP call centers for payment and coverage policies for residents in NFs. In addition, the location codes for services may not indicate NFs as permanent residences, which create billing confusions.

In response to these coordination-of-benefits issues, CMS has issued policy guidance, but not specific guidance for telecommunication standards. The standards have been referred to the National Council for Prescription Drug Programs (NCPDP), which is the standards organization for electronic pharmacy transactions, to develop proposals for handling claims.

## Q 24:71 What are the exceptions and appeals process issues for LTC under Part D?

The difference between LTC and PDP formularies leads to uncertainties in coverage and payment. For example, there is a conflict between the LTC pharmacy negotiation with manufacturers for purchase pricing and rebates versus the agreements of the same manufacturers with PDPs. However, CMS specifically identifies rebates to LTC pharmacies as contrary to the spirit of the Medicare law. As a result, rebates must be included in the price concessions and bids between LTC pharmacies and PDPs.

Of particular concern are utilization management requirements for psychotherapeutic medications and the impact of copay tiers on specialty pharmaceuticals that commonly exceed limits of \$500 in monthly costs.

## Quality Measures

### Q 24:72 Why does Part D have a quality focus?

Essentially, quality variations are much higher in health care than in other national industries. Nominal quality differences are reported in other industries such as airlines, banking, and manufacturing; however, the quality “gap” may be as high as 20 percent on existing measures within health care. Consider the following annual statistics as indication of the importance of the quality initiatives:

- Forty-four thousand to 98,000 deaths caused by medical errors are reported annually.
- Seven thousand inpatient deaths due to medication errors are reported annually, at a cost of \$77 billion.
- Only 70 percent of adults with chronic conditions receive recommended medications.

[National Committee for Quality Assurance, *The State of Health Care Quality 2004–5*]

### Q 24:73 How is quality measured in pharmacy programs?

Quality measures fall under three broad categories in pharmacy programs:

1. Administrative measures—this is the basis of Joint Commission Accreditation of Healthcare Organizations (JCAHO) measures that focus on inpatient pharmacy operations
2. Operational measures—these are typical of PBM contracts that focus on computer-generated information and customer service requests
3. Integrated health quality measures—these are typical of Health Plan Employer Data and Information Set (HEDIS) measures that focus on patient care from a medical perspective and include pharmacy

measures for specific diseases

## Q 24:74 What is the quality mandate in MMA and Part D?

There are 131 references to quality in the MMA. These include standards for DME suppliers, Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories, hospitals, and long-term care facilities. MMA extends the oversight of Quality Improvement Organizations to Medicare Parts C and D. Finally, MMA includes funding for demonstration projects.

Specific language for PDPs is contained within Part D—PDPs must have “quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.” Furthermore, 30 days prior to the open enrollment period, the secretary of Health and Human Services (HHS) must publish the following information:

- Plan premiums and beneficiary cost shares
- Comparative plan quality and performance
- Results of member satisfaction surveys

## Q 24:75 What are the Part D quality reporting measures?

The following is a listing of measures originally established in 2006:

- Enrollment and disenrollment
- Claim reversals
- MTM beneficiary eligibility and enrollment
- Generic dispensing rate
- Grievances
- Prior authorization, step edit, and exceptions
- Appeals
- Call center measures
- Overpayment
- Rebates, discounts, and price concessions
- Financial and solvency statistics

## Q 24:76 What is the Medicare quality initiative?

Part D requires that medication measures be developed that demonstrate the quality of drug use for areas determined by CMS. The measures must be based on clinically supported research and evaluated by a technical expert panel. The measures must consider the technical and data limitations of PDPs. CMS draft guidance for developing these measures occurred in spring 2006.

The ideal measures for quality must be based on the Institute of Medicine (IOM) domains of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitability. They must be based on scientific evidence, and there must be consistency within the guidelines. They must be applicable to one or more purposes: quality improvement; patient safety; evaluating and monitoring clinical and economic impacts; and oversight for the purposes of controlling fraud, abuse, and waste. Finally, there must be public reporting of the measures.

## Q 24:77 How do the ideal measures apply to pharmacy programs under Part D?

The ideal measures in pharmacy programs are directed to the following areas:

- Improving the use of appropriate therapies for the targeted disease states in accordance with accepted treatment guidelines and regimens
- Reducing the potential for adverse events that may result from drug therapy
- Quantifying differences in quality and cost across plan sponsors
- Avoiding waste, fraud, and abuse

All these procedures must be measured and reported within the context of what is feasible for use in PDPs and MA-PDs, providing challenges for measurement of these quality criteria. Most notably, the data is limited to claims data from multiple data systems and sources (e.g., claims processing vendors, PBMs, PDPs, MA-PDs) that use complex and nonstandard data sets for pharmacy and medical claims.

## Q 24:78 Are there any currently available frameworks for basing the collection and evaluation of quality measures?

The Academy of Managed Care Pharmacy (AMCP) published its *Pharmacy's Framework for Quality in 21st Century*. This framework is a tool to assist PDPs, MA-PDs, and pharmacies to diagnose and assess their quality gaps. In addition, JCAHO, Utilization Review Accreditation Committee (URAC), National Committee for Quality Assurance (NCQA), and HEDIS quality measures are available to assess quality gaps.

## Audit Issues

### Q 24:79 What is the rationale for CMS auditing of services?

In a statement on Medicare Program Integrity by CMS's chief financial officer, Timothy Hill, before the House Ways and Means Health & Oversight & Investigations on March 8, 2007, the following rationale was given for Medicare program oversight:

Given the staggering size of Medicare program expenditures, even small payment errors can represent a significant impact to the Federal treasury and taxpayers. For this reason, CMS, as part of a sound financial management strategy, has a relatively long history of using improper payment calculations as a tool to preserve the fiscal integrity of Medicare. CMS uses improper payment calculations to identify the amount of money that has been inappropriately paid, identify and study the causes of the inappropriate payments, and focus on strengthening internal controls to stop the improper payments from continuing.

### Q 24:80 What are the CMS requirements for Part D audits of MA-PDs and PDPs?

On November 13, 2006, CMS provided the *Final MA-PD and PDP Part D Audit Guides for Part D Program Audits*. This document gave guidance for the compliance audits mandated in Part D regulations in 42 C.F.R. Section 423 and other CMS standards. Specific reference was made to CMS audit guides:

- Medicare Advantage Prescription Drug Plan Sponsors Part D Audit Guides

- Prescription Drug Plan Sponsors Part D Audit Guide

[[http://www.cms.hhs.gov/PrescriptionCovContra/08\\_RxContracting\\_ReportingOversight.asp#TopOfPage](http://www.cms.hhs.gov/PrescriptionCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage)] Drug

## Q 24:81 What are the CMS audit standards?

CMS conducts regularly scheduled desk and on-site program audits to assess its compliance with the Part D regulations: 42 C.F.R. Sections 422 and 423, and other standards. These audits are based on the following references:

- 42 C.F.R. Sections 422 and 423
- Prescription Drug Benefit Manual
  - Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
  - [http://www.cms.hhs.gov/PrescriptionDrugCovContra/08\\_RxContracting\\_ReportingOversight.asp#TopOf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOf)

## Q 24:82 What are CAPs?

*Corrective Action Plans (CAPs)* provide an opportunity to identify risk areas within an organization. The CAP text on the CMS Web site can provide insight into what CMS considers inadequate and what improvements should be made by the organization.

Areas commonly emphasized by CMS are:

- Grievances, Coverage Determination, and Appeals
- Marketing
- Formulary, Transition Process, and Pharmacy and Therapeutics (P&T) Committee

CAP descriptions and criteria can be found at:

- <http://www.cms.hhs.gov/MCRAAdvPartDENrolData/CAP/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=ascending &itemID=CMS1203697&intNumPerPage=10>

## Q 24:83 What are the most commonly emphasized risk areas requiring CAPs?

The Gorman Group has identified the top issues that are frequently targeted for CAPs. These are:

1. Coverage Determinations
  - (a) CD04: Coverage Determinations for Payment (Paper Claims)
  - (b) CD02: Coverage Determination Policies and Procedures (P&Ps)
  - (c) CD09: Timely Notice and Notice Content of Coverage Determinations
2. Grievances
  - (a) GV01: Correct Grievance Categorization
  - (b) GV04, GV05: Grievance Notice and Method of Response
  - (c) GV02: Grievance P&Ps
3. Redeterminations
  - (a) RE05: Redetermination Notice Timeliness

(b) RE07: Timely Notice for Expedited Redeterminations and Requests for Information

4. Formulary Change Notification – FM03

In addition to the above, the Office of the Inspector General (OIG) work plans for fiscal year 2008 include an evaluation of CMS's oversight of marketing and sales of Medicare Advantage plans, including the adequacy of sanctions against non-compliant plans. This could lead to more stringent auditing of plans by CMS.

### Q 24:84 What is the CMS anti-fraud, waste & abuse (F-W-A) program?

CMS has established an F-W-A program to detect and act on potential fraud and abuse cases. The F-W-A program consists of using contractors to detect fraud (so-called MEDICs); outreach to law enforcement, PDPs, and consumer groups; and basic tips for consumers.

### Q 24:85 What are *MEDICs*?

*MEDICs*, or Medicare Rx Integrity Contractors, are companies that specialize in detecting fraud, waste, and abuse. CMS has contracted with Delmarva Foundation for Medical Care, EDS, IntegriGuard, Livanta, Maximus Federal Services, NDC Health, Perot Systems Government Services, and SAIC to provide these services. These contractors analyze data to detect potential fraud, investigate potential fraud and unusual activities, conduct complaint investigations, and develop and refer cases to law enforcement.

### Q 24:86 What is the sponsor's responsibility for F-W-A?

Sponsors must establish F-W-A programs. These programs must be based on written policies and procedures. Sponsors must have a compliance officer and responsible committee that have oversight of their monitoring and audit program. They must establish programs for effective training as well as for effective lines of communication. They must publicize their disciplinary guidelines, and they must respond promptly to F-W-A offenses.

The sponsor's F-W-A pharmacy audit program must include routine comprehensive audits and data analysis to detect problems. The comprehensive pharmacy audits must include reviews of prescriptions, invoices, pharmacy licenses, pharmacy signature logs, purchase logs, claims transaction records, contracts, rebates, and discounts. In addition the sponsor's program must include prescription data analysis to establish baselines, and identify potential errors.

### Q 24:87 What is the sponsor's responsibility regarding quality programs?

Sponsors are required to establish quality assurance programs under 42 C.F.R. Section 423.153c(1). This mandate requires sponsors to establish quality assurance systems and measures that reduce medication errors and adverse drug reactions. The sponsor must require providers to take responsibility for minimizing these problems.

### Q 24:88 What is operation *CYBERx*?

The Drug Enforcement Agency (DEA) has been given responsibility to establish a multi-faceted drug enforcement task force known as *CYBERx*. This task force has the responsibility to detect rouge Internet pharmacies and to refer them for prosecution if possible.

## Q 24:89 What are PERMs?

The *Payment Error Rate Measurement (PERM)* Initiative was defined in the Improper Payments Information Act of 2002 (IPIA; Pub. L. No. 107-300). This law required federal agencies to annually review their programs and report improper payments to Congress. Medicaid was identified as a program at risk for significant erroneous payments. As a result, CMS was required to provide reports of erroneous payments under PERMs within their annual budget request. This includes CMS's responsibility for Part D erroneous payments. To comply with congressional reporting requirements, CMS established a national strategy based on contracting with a statistical company (The Lewin Group), a documentation and database company (Livanta LLC), and a medical review contractor. These contractors review Medicare Part D claims for whether they were processed correctly, whether the service was medically necessary, coded correctly, and properly paid or denied.

## Q 24:90 What aids does CMS provide for consumers to prevent fraud and abuse?

CMS provides consumers with several help lines and Web sites to protect their private information and to report fraud and theft of their private information. These methods include:

- A 1-800-MEDICARE help line;
- FTC ID Theft hotline—877-438-4338;
- *Quick Facts About Medicare Prescription Drug Coverage and Protecting Your Personal Information*—[www.medicare.gov/Publications/Pubs/pdf/11147.pdf](http://www.medicare.gov/Publications/Pubs/pdf/11147.pdf);
- Referring potential theft to local law enforcement; and
- Referring consumers to their local State Health Insurance Assistance Program (SHIP).

## Coordination of Benefit (COB) Issues

### Q 24:91 What guidance has CMS provided for coordinating benefits between Part D and other insurance?

The fundamental guiding principle is that MMA requires coordination between CMS, State agencies, insurers, and employers to ensure that the benefits provided to Part D beneficiaries are maximized.

States have special coordination concerns because of their dual status as employers and insurers.

### Q 24:92 Who pays first, if the beneficiary has Part D and other insurance?

The following table summarizes the answer to this question.

Part D plus ...	Pays First
SPAP (State Pharmaceutical Assistance Programs)	Part D
Retiree covered under former employer's Group Health Plan (GHP)	Part D
Also covered under the GHP of	Part D

retired spouse

Retiree GHP + SPAP	(1) Part D, (2) GHP, (3) SPAP
Medicaid	Either Part D or Medicaid
Retiree GHP + Medicaid	Part D, then GHP GHP, then Medicaid
Currently working with coverage thru GHP	GHP, then Part D
Covered under GHP of actively working spouse	GHP, then Part D
Covered under Workers' Compensation (WC)	WC, then Part D for injury-related Rx
No fault or liability coverage (NF/LC)	NF/LC, then Part D for injury/illness related Rx

## Q 24:93 What are the payment categories for drugs that are covered under Parts A and B of Medicare?

The following summarizes the categories of payments made to providers for Parts A and B drugs:

- Bundled payments to acute care hospitals and SNFs generally cover all Rx provided during the stay
  - Part A: Rx bundled with payments to facility
    - Exception to inpatient hospital stays: Clotting factor
    - Exception to SNF stays: High-cost chemotherapy
- Payments to physicians for drugs and biologicals that are administered by infusion or injection
- Does not cover self-injectables
- Does not cover most outpatient Rx

## Q 24:94 What drug categories are specifically covered under Part B of Medicare?

The following is a list of medications and medication categories covered under Part B. These medications are billed separately from professional services.

- DME supply drugs
- Immunosuppressive medications
- Hemophilia clotting factors
- Anti-cancer drugs – oral
- Anti-emetic drugs – oral
- Pneumococcal vaccine
- Antigens
- Erythropoietin (EPO)
- Hepatitis B vaccine

- High risk: ESRD, Rx Factor VIII/IX, institutions for mentally handicapped, household mate of HBV carrier, homosexual men, illicit injectable drug abusers
- Intermediate risk: staff of institutions for mentally handicapped, workers in healthcare institutions with frequent blood or blood derived body fluid contact
- Parenteral nutrition
- IVIG in home
- Influenza vaccine

## Q 24:95 What drugs are covered/not covered under Part B that are prescribed as a consequence of professional services?

The following is a list of medications and medication categories covered under Part B that are prescribed as a consequence of Part B covered professional services. These medications are billed separately from the professional services billing.

- Drugs furnished “incident” to a professional service
- Separately billable ESRD
- Hospital outpatient department separately billable
- Drugs covered as supplies or “Integral to a Procedure”
- Blood

In addition, certain drugs are furnished as part of a service in provider settings. These drugs are included in the Part B billing.

- Drugs packaged under hospital outpatient prospective payment system
- ESRD facilities included in Medicare’s ESRD composite rate
- Osteoporosis drugs provided by home health agencies
- Critical Access Hospitals (CAH) outpatient department
- Rural Health Clinic (RHC)
- Federally Qualified Health Centers (FQHC)
- Community Mental Health Centers
- Ambulances
- Separately billable drugs provided by Comprehensive Outpatient Rehabilitation Facilities (CORF)

## Q 24:96 Which medications are covered under Medicare Part D?

CMS provides the following definitions for medications covered under Part D:

A Part D covered drug is available only by prescription, approved by the Food and Drug Administration (FDA) (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Act), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act).

- A covered Part D drug includes prescription drugs, biological products, insulin as described in specified paragraphs of section 1927(k) of the Act, and vaccines licensed under section 351 of the

Public Health Service Act.

- The definition also includes “medical supplies associated with the injection of insulin (as defined in regulations of the Secretary). We define those medical supplies to include syringes, needles, alcohol swabs, and gauze.”
  - The definition of supplies associated with the delivery of insulin to the body was expanded to include injection and inhalation, effective June 9, 2008.
- Effective January 1, 2008, fees for vaccine administration are included in Part D.

## Q 24:97 Which medications are excluded from coverage under Medicare Part D?

The following medications, and categories of medications, are not covered under Medicare Part D:

- Medications available under Parts A or B (even though a deductible may apply)
- Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents. The drugs or classes of drugs that may currently be otherwise restricted under Medicaid include:
  - Agents when used for anorexia, weight loss, or weight gain
  - Agents when used to promote fertility
  - Agents when used for cosmetic purposes or hair growth.
  - Agents when used for the symptomatic relief of cough and colds
  - Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
  - Nonprescription drugs
  - Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale
  - Barbiturates
  - Benzodiazepines
  - Exclusions added, effective June 9, 2008:
    - Drugs used to treat erectile dysfunction (ED)
    - Drugs used to treat morbid obesity

## Q 24:98 Can GHPs cover a Part D excluded drug?

Drug plan sponsors can generally include the Part D excluded medications as part of supplemental benefits, provided they otherwise meet the definition of a Part D drug. For example, because non-prescription OTC drugs do not otherwise meet the definition of a Part D drug, they may not be included as part of supplemental benefits; however, OTC medications may be covered under the following condition:

- Under certain conditions as part of a utilization management program (including a step-therapy program), non-prescription drugs can be provided at no cost to enrollees.
- The cost of these drugs to the plan would be treated as administrative costs under such programs.

## Q 24:99 What is the impact on State Health Benefits from the inclusions and exclusions of medications under Medicare Part D?

Drug benefits will now be available or coordinated with Part D for the following populations:

- Benefits provided to state employees, retirees, and dependants, many of whom may be Medicare beneficiaries
- Medicaid coverage provided to low-income beneficiaries, many of whom may be Medicare dual-eligibles who will now receive most drug coverage from Medicare Part D
- Supplemental drug coverage offered to seniors through the State Pharmaceutical Assistance Programs (SPAPs). Coordination with SPAPs is a high priority for CMS

## Q 24:100 Who is the CMS contractor for oversight of COB, and what are their responsibilities?

In 1999, CMS named Group Health, Inc. (GHI) as the COB contractor. The COB contractor consolidates activities to support the collection, management, and reporting of all health insurance coverage of Medicare beneficiaries to implement an improved plan for coordinating Medicare benefits with other insurance coverage.

As part of its contract, the COB contractor coordinates the following activities:

- Various questionnaires sent to beneficiaries, employers, providers, and insurers about group health plan coverage
- Voluntary Data Sharing Agreements (VDSAs) among CMS and employers and insurers to exchange enrollment information on Medicare beneficiaries
- Coordination of Benefits Agreements (COBAs) between CMS and supplemental health insurers to coordinate the payment of claims after Medicare has made its payment
- Share drug enrollment data by:
  - Facilitating the calculation of TrOOP by the Part D Plans
  - Facilitating billing in the appropriate order at the pharmacy point of sale
  - Ensuring that SPAPs have the information they need to develop their benefit structures
  - Ensuring that Medicaid agencies know which of their beneficiaries are dual-eligibles
  - Simplifying the exchange of enrollment files for employers claiming the Employer Subsidy

## Q 24:101 What are voluntary data sharing agreements (VDSAs)?

VDSAs were originally developed to enable CMS, insurers, and employers to coordinate benefits and reduce mistaken payments and administrative expenses. They also allow an exchange of employer GHP coverage information for Medicare entitlement information. Concurrently, they allow GHPs to meet Medicare Secondary Payer reporting requirements and provide them with Medicare entitlement information so they can determine when Medicare should be the primary payer. VDSAs also collect drug coverage information that is supplemental to Medicare for TrOOP facilitation, in exchange for Part D entitlement information. Finally, they allow employers to use VDSAs to submit drug coverage enrollment files to claim the employer subsidy.

## Q 24:102 How do State Pharmaceutical Assistance Programs (SPAPs) share data?

They use a process similar to the VDSA program so that SPAPs can receive Medicare Part D entitlement information. The process is as follows:

- The SPAP would submit a monthly electronic file of all its enrollees to the COB contractor.
- The COB contractor would respond with a file detailing the Medicare Part D entitlement of those enrollees. This information will include:
  - Part D entitlement dates;
  - the enrollee's Part D Plan;
  - the monthly Part D Plan premium amount; and
  - effective dates and level of the low-income subsidy.

## Q 24:103 What are coordination of benefits agreements (COBAs)?

CMS consolidated the claims crossover Trading Partner Agreements with Medicare contractors into the COBA process at the COB contractor. These agreements are negotiated and maintained between CMS and supplemental health insurers (and Medicaid State Agencies, and their fiscal agents) for the exchange of entitlement and paid claims data. The overall goal of this process is to (1) coordinate correct claim payments by Medicare and supplemental health insurers; (2) to report other drug coverage that is supplemental to Part D to facilitate the tracking of TrOOP and to facilitate billing at the pharmacy.