CONTEMPORARY SUBJECT

Medicare Part D: Selected Issues for Plan Sponsors, Pharmacists, and Beneficiaries in 2008

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ABSTRACT

BACKGROUND: The Medicare Drug Benefit (Part D) was implemented on January 1, 2006. The principal emphasis in the first year was education of beneficiaries as part of the effort by health plans and prescription drug providers to enroll beneficiaries. There was continued emphasis on enrollment in the second year in 2007, with some refinement of the benefit such as removal of coverage for erectile dysfunction drugs.

OBJECTIVE: To (1) review policy statements released by the Centers for Medicare & Medicaid Services in 2007 for the Medicare drug benefit, (2) compile an abridged version of the highlights from the policy statements, and (3) describe implications that affect Part D plan sponsors, pharmacists, and beneficiaries in 2008.

METHODS: We reviewed more than 200 policy statements, including guidance, memos, announcements, and other communications that were released between January 1, 2007, and September 30, 2007. We selected those policy statements that described substantive changes in the Medicare drug benefit and summarized those that were determined to be most relevant to plan sponsors, pharmacists, and beneficiaries for 2008.

RESULTS: Policy statements summarized in this article fall into 12 categories that have the greatest relevance to plan sponsors, pharmacists, and beneficiaries in 2008: (1) the standard drug benefit, (2) redetermination of low-income subsidy (LIS) status, (3) reassignment of some LIS beneficiaries whose plan premium exceeds the 2008 benchmark by more than $1, (4) allowable marketing activities for pharmacists, (5) Medicare Advantage special enrollment period, (6) member transition process, (7) "best available evidence" for determination of LIS, (8) formulary review process, (9) redefinition of specialty-tier medication from a cost threshold of $500 in 2007 to $600 in 2008, (10) drugs that have a limited distribution network (i.e., "specialty" pharmacy drugs), (11) formulary reference file, and (12) transfer of reimbursement of the administration fee for Part D vaccines from Medicare Part B to Part D.

CONCLUSION: The Medicare drug program continues to be refined in 2008, including coverage of the cost of Part D vaccines and their administration fee entirely within Part D. Pharmacists will continue to be an integral part of the success of Medicare Part D in 2008 by being informed of the many changes to the benefit and adapting to these policies and regulations in a way that allows beneficiaries maximum access to the improved features and necessary medications.

J Manag Care Pharm. 2008;14(1):50-60

What is already known about this subject

- The Medicare Prescription Drug Improvement and Modernization Act of 2003 provided the framework for the Medicare Part D program. Anyone who is eligible for Medicare may elect to participate in this federally funded program.
- Medicare Part D, which began on January 1, 2006, is provided by private "at risk" entities called prescription drug plans (PDPs). Plans that combine Medicare Advantage (medical) coverage with the prescription drug benefit are known as MA-PD plans.
- PDPs develop formularies, recruit membership, and manage prescription use. Oversight of PDPs is provided by the Centers for Medicare & Medicaid Services.
- The United States is divided into 34 geographic PDP regions. Each region contains 1 or more states. Each PDP may apply to provide prescription coverage for 1 or many regions.
- Low-income beneficiaries formerly covered under Medicaid or low-income seniors covered by a state pharmacy assistance program may have their monthly premiums and copays either waived or reduced. Beneficiaries who are eligible for both Medicare due to age or disability and Medicaid due to financial status are known as dual eligibles.
- Sixty-five percent of Part D beneficiaries in 2007 were covered by the standard drug benefit or one that was actuarially equivalent.

What this study adds

- The standard benefit design coverage phase thresholds have changed for 2008: (1) the annual deductible increased 3.8% to $275 from $265; (2) the initial coverage limit is $2,510, up 4.6% from $2,400; and (3) beneficiaries must incur $4,050 in true out-of-pocket (TrOOP) costs before entering the catastrophic coverage phase, which is up 5.2% from $3,850 in 2007. After beneficiaries have incurred $4,050 in TrOOP in 2008, the cost-share is the greater of $2.25 for generics and $5.60 for brands or 5% of drug cost.
- Cost-sharing for dual-eligibles increased by 5% for generic drugs in 2008 from $1.00/$3.10 (generic/brand) to $1.05/$3.10. Cost-sharing for other low-income subsidy (LIS) beneficiaries increased by 4.7% from $2.15/$5.35 (generic/brand) to $2.25/$5.60.
- The qualifying criterion for specialty-tier prescriptions increased by 20% from $500 per month in 2007 to $600 per month in 2008.
- Beginning in 2008, drugs restricted to a limited distribution network, known as specialty pharmacy medications, must be identified on Part D sponsors' formulary submissions.
- Coverage of Medicare Part D vaccine *administration* fees moved from the Part B benefit to the Part D benefit in 2008. This is an important opportunity for pharmacists to administer Part D vaccines and bill Part D plans directly for the vaccine and administration.

The Medicare prescription drug benefit was implemented on January 1, 2006. The first year of the benefit was marked by beneficiary education and enrollment. The Centers for Medicare & Medicaid Services (CMS), Part D sponsors, pharmacists, and beneficiaries all worked toward understanding the benefit, ensuring optimum enrollment, and facilitating implementation and coverage of necessary medications. The year was not without challenges, but by the end of 2006, 22.5 million beneficiaries were enrolled in a Medicare Part D plan.[1] Approximately 75% of beneficiaries stated that they were satisfied or very satisfied with their Part D plans.[2] After almost 1 year of experience with Medicare Part D, beneficiaries were given the opportunity to review their coverage and switch Part D plans during the open enrollment period from November 15 through December 31, 2006. Only 6% of beneficiaries reported switching plans during the open enrollment period.[3]

The second year of Medicare Part D implementation in 2007 included changes to the standard prescription drug benefit, extension of the open enrollment period for Medicare Advantage-only plans, coverage exclusion for erectile dysfunction drugs, clarification of payment for Part D vaccines and their administration, and implementation of the national provider identifier for pharmacists and other providers.[4] There was a continued emphasis in 2007 on enrollment, particularly among beneficiaries who were eligible for the low-income subsidy (LIS), also known as Extra Help; enrollment in Medicare Part D plans increased by 7.6% to 24.2 million beneficiaries.[1] A special enrollment period was granted to those who qualified for LIS in 2007, and any late enrollment penalties were waived.[5] Four million Medicare beneficiaries, 11% of all beneficiaries, lacked prescription drug coverage in 2006 and 2007. CMS faces a continuing challenge to reach out to unenrolled individuals so that everyone eligible for Part D is covered.

The third year of the program in 2008 involves continued refinement of Medicare Part D with an emphasis on offering improved choices to beneficiaries, such as a "free first fill" program and "limited gap coverage" in the "donut hole" as part of changes in the standard benefit. Developments of note in 2008 for the standard benefit and 11 other categories are described below.

1. How Did the Standard Benefit Change in 2008?

There was again a change in the standard prescription drug benefit (defined by CMS as the minimum required plan design) and LIS patient cost-sharing amounts in 2008. Each plan sponsor must offer one standard benefit design, or one that is actuarially equivalent. Annual updates to the standard benefit design are statutory requirements of the Social Security Act and will continue throughout the life of the program. These changes are tied to 2 statutorily defined indexes—the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary (annual percentage increase) and the Consumer Price Index (CPI).[6]

The first indexing method, the annual percentage increase, is used to update the following cost-share requirements of the Part D benefit (see table and footnotes):

1. The deductible, initial coverage limit, and out-of-pocket threshold for the defined standard benefit
2. Minimum copayments for costs above the annual out-of-pocket threshold
3. Maximum copayments below the out-of-pocket threshold for full LIS-eligible enrollees (≤ 100% federal poverty level [FPL])
4. The deductible for partial LIS-eligible enrollees (100% to 150% of the FPL)
5. Maximum copayments above the out-of-pocket threshold for partial LIS-eligible enrollees

The second indexing method, the CPI, is used to determine the maximum cost-share amount for dual-eligible beneficiaries (eligible for both Medicare and Medicaid) that fall at or below 100% of the FPL. These changes for the upcoming year are outlined in the Table.

Base Beneficiary Premium

The base beneficiary premium is calculated by CMS each year and is used in determining the late enrollment penalty. In 2008, the base beneficiary premium increased 2.1% from $27.35 to $27.93.[7] The actual Part D premiums paid by beneficiaries equal the base beneficiary premium adjusted by a number of factors, such as application of the low-income premium subsidy (dual-eligibles receive full-premium subsidy). In practice, actual premiums paid by beneficiaries vary widely among Part D plans, but the average monthly premium is $25 in 2008, up 13.6% from $22 in 2007.[3] The base beneficiary premium is used to calculate the late enrollment penalty, if incurred by a beneficiary. For example, if a beneficiary missed the original May 15, 2006, deadline to sign up for Part D and did not sign up until December 15, 2006, he or she incurred a 1% penalty for each month not joined; that is, for 7 months (June-December 2006). The penalty is permanent and is recalculated each year as the base beneficiary premium changes. In 2008, the penalty will be 7% of $27.93, or $1.96 *in addition to* the normal monthly premium. Late enrollment penalties are waived for beneficiaries who are eligible for LIS (see below).

Low-income Subsidy

The amount of LIS or "extra help" a beneficiary receives is based on his or her income and resources. In 2007, a beneficiary with an annual income below $15,315 ($20,535 for a married couple living together) and resources of less than $11,710 ($23,400 for a married couple living together) qualified for extra help.[8] These income and resource ceilings are based on the FPL and will be updated in early 2008 when the FPL is updated. CMS extended the special enrollment period in which the late enrollment penalty is waived for LIS-eligible beneficiaries who enroll in a Part D plan through the end of 2008.[5] LIS status means that beneficiaries

TABLE 2008 Changes to the Medicare Part D Standard Benefit[a]

Benefit Parameters	2007	2008
Annual deductible	$265	$275
Initial coverage limit	$2,400	$2,510
TrOOP costs	$3,850	$4,050
Catastrophic threshold	$5,451	$5,726
LIS copayments	generic/brand	generic/brand
Institutionalized beneficiaries	$0/$0	$0/$0
Up to or at 100% FPL	$1.00/$3.10	$1.05/$3.10
Other LIS	$2.15/$5.35	$2.25/$5.60

[a] *The standard benefit design includes the annual deductible, which is the amount of money a beneficiary must spend on medications before the plan starts to pick up any portion of medication expenses. Once the member has satisfied the annual deductible, the member enters the initial coverage phase. As part of the standard benefit design, the plan pays 75% of prescription costs, and the member pays 25% during the initial coverage phase up to the initial coverage limit, above which there is a gap in coverage referred to as the "donut hole" in which the beneficiary pays 100% of medication costs until the TrOOP costs push the beneficiary into the catastrophic phase. For costs above the catastrophic threshold, the beneficiary is responsible for only a small portion of cost-sharing for the remainder of the benefit year. Plan sponsors can offer the standard benefit design or may vary their design as long as it is actuarially equivalent to the basic coverage. Sponsors may offer a wide variation of coverage plans, which could waive the deductible, charge copayments rather than coinsurance, or offer a combination of both. In 2007, many plan sponsors offered "enhanced" benefits, including generic drug coverage in the coverage gap ("donut hole") as well as inclusion of certain Part D excluded drugs such as benzodiazepines or over-the-counter drugs.*

FPL=federal poverty level, defined as an annual income in 2007 below $10,210 for an individual or $13,690 for a couple; LIS=low-income subsidy, available to beneficiaries with annual income below 150% of the FPL (i.e., $15,315 for an individual or $20,535 for a couple) and resources below $11,710 for an individual or $23,410 for a couple); TrOOP=true out-of-pocket.

pay minimal copayments (see Table) and are not subject to the coverage gap (donut hole).

Free First Fill

The Final 2008 Call Letter, a CMS document outlining the agency's guidance on the Part D programs, describes other benefit variations that plans may use in 2008.[9] One of these variations is a free first fill program. As the name implies, plans may offer free first fills on certain medications such as generic drugs as part of a generic use incentive program to increase generic utilization rates. Plans that offer free first fills are required to submit a separate formulary file that will be reviewed by CMS and to display this list on their Web sites and in other marketing materials.

Coverage in the Donut Hole—Limited Gap Coverage

It has been common for plans to offer an enhanced benefit with coverage of generic drugs through the coverage gap (donut hole). Previously, plans notified their members if all medications in the generic copayment tier were covered in the donut hole for a specified copayment amount. In 2008, CMS allows another plan design variation called limited gap coverage in which plans may cover a subset of drugs, rather than an entire formulary copayment tier, in the donut hole. For example, plans may identify a specific list comprising a small or large number of brand medications that are covered in the donut hole. This variation allows plans to offer some brand name medication in the donut hole while limiting their financial risk. For plans that choose this option, a separate formulary file is submitted and reviewed by CMS to ensure that statutory discrimination provisions are not violated. Another form of limited gap coverage allowed by CMS in 2008 is a maximum dollar amount of coverage (e.g., $500) in the donut hole, thereby limiting the plan's financial risk.

In 2008, plans are encouraged by CMS to offer drug benefit offerings that include brand name drug coverage in the donut hole. Plan sponsors are allowed to offer only 2 drug benefit offerings per region, unless 1 of the plan offerings provides coverage in the donut hole. If a plan submits bids, including a benefit that offers coverage of all generics and brands in the donut hole, up to 4 different offerings per region will be considered by CMS as long as they have meaningful variations. Among the 17 national plans available in 2008, 12 offer coverage of generics in the donut hole.[10] None of the national plans offer coverage of brand drugs in the donut hole in 2008.

Implications

The Medicare Part D standard benefit serves as a reference point for benefit design. In 2007, 14% of Part D beneficiaries were in plans with the standard benefit and another 51% were in plans that were actuarially equivalent to the standard benefit. The remaining 35% of beneficiaries selected a plan that offered an enhanced benefit.[1] Each year plan sponsors must explain to beneficiaries the changes in the standard benefit design and LIS copayments. These annual changes are mandated by the Social Security Act and updated by CMS accordingly each benefit year. Plan sponsors provide this information to beneficiaries in print and through their Web sites. However, the task of explaining the changes in LIS copays and out-of-pocket thresholds will most likely end up with the pharmacist when the patient receives an unexpected copay or is in the coverage gap longer than the patient expected. In addition, new plan variations allowed by CMS such as free first fills and limited gap coverage will most likely not gain wide acceptance by plan sponsors in 2008.

Although the options sound good in concept, there are operational and patient education considerations. Significant systems coding and testing are required to ensure the benefit processes perform as intended. For free first fills, plans need to anticipate and manage issues, such as what constitutes a first fill and how is this communicated to beneficiaries, including the ones who are already taking medications included on the free first fill list. For limited gap coverage such as certain brand medications, significant beneficiary education is necessary to manage expectations

of coverage in the donut hole. Most plans will likely take a wait-and-see approach as they gather data to determine the marketing and operational costs of offering enhancements and variations to the Medicare Part D standard benefit.

2. Do Beneficiaries Who Qualified for the LIS in 2007 Automatically Qualify in 2008?

CMS performs an annual redetermination of LIS deemed status, known as "re-deeming."[11] The re-deeming process determines who continues to be deemed LIS for 2008 and whether the individual's copayment level changes or remains the same. Individuals reported as dual-eligible beneficiaries in July 2007 have had their LIS-deemed status extended to December 31, 2008. The copayment level for 2008 is based on LIS status as of July 2007. Individuals who were previously deemed eligible for LIS but who did not appear eligible in July 2007 are not deemed for 2008. Their deemed status expired on December 31, 2007. CMS mailed notices in September 2007 to the non-deemed beneficiaries along with a LIS application to assist the individual in reestablishing eligibility for 2008. Individuals who became eligible for the LIS for the first time between July 2007 and December 2007 were deemed eligible through December 31, 2008. In addition to a written communication from CMS, an annual notice of change was sent to all beneficiaries from their plan sponsors in 2007 that outlined changes to their benefit and indicated their deemed status.

Implications

Pharmacists should encourage beneficiaries to carefully read any information received from the government regarding their LIS status. Individuals who need to reapply for LIS should have done so in 2007 in order to receive extra financial help by the beginning of 2008. Beneficiaries who lose LIS status in 2008 can obtain information on reestablishing eligibility at www.ssa.gov or by calling the Social Security Administration (SSA) at 800.772.1213.

3. Why is CMS Re-assigning Some LIS Beneficiaries to New Part D Plans?

Each year, the average plan premium bid amounts are calculated for each prescription drug plan (PDP) region to determine the regional benchmark. Dual-eligible beneficiaries receive full-premium subsidy and are assigned by CMS to plans that are at or below the benchmark for the region they live in. Since the benchmark changes each year with the new bids and is difficult to predict, CMS allows some flexibility in an attempt to prevent member disruption. Plans that exceed the regional benchmark by $1 or less are considered to meet the de minimis amount and retain their current dual-eligible members but may not receive new auto-assignments. Plans that exceed the de minimis amount will lose their dual-eligible members who will be reassigned to plans at or below the regional benchmark for their region.[12]

Implications

It is estimated that up to 1.6 million full-premium subsidy beneficiaries may need to be reassigned in 2008.[13] Because benchmarks and plan premiums vary by region, some plans may meet the benchmark standard in 1 or more regions but not in others. Pharmacists can identify which plans in their region meet the benchmark by viewing the plan Landscape Source spreadsheet available from CMS.[14] Although beneficiaries will receive notification of this change in the mail, some dual-eligibles may not be aware of their reassignment until they attempt to get their prescriptions filled in 2008. Pharmacists need to obtain new plan information from the beneficiary in order to successfully submit an electronic claim to the new plan for payment. If the beneficiary is unaware of this new plan information and is unable to locate it, the pharmacist may attempt to obtain this information via an electronic ("E1") transaction. The pharmacy can submit some basic patient information (e.g., first name, last name, date of birth, zip code, etc.) in a real-time query through the pharmacy processing system to obtain eligibility and plan information. This information is obtained from a facilitator that is contracted by CMS. Eligibility information is provided to the facilitator by CMS and is updated nightly. Reassignment of LIS beneficiaries to new Part D plans can create additional work for pharmacists and contribute to potential delays in the pharmacy. If a dual-eligible beneficiary is not satisfied with the plan to which he or she has been reassigned, he or she can switch to another plan at any time during the year. Pharmacists should direct beneficiaries to www.medicare.gov or 800.MEDICARE for assistance.

4. What Marketing Activities Are Allowable for Pharmacists?

In 2007, CMS clarified the allowable marketing activities for providers, provider groups, and pharmacies.[15] CMS emphasized consistent policy, which is that providers and pharmacies may not "market" to beneficiaries, defined as "steering, or attempting to steer, an undecided potential enrollee towards a plan, or limited number of plans, and for which the individual or entity performing marketing activities expects compensation directly or indirectly from the plan for such marketing activities." However, CMS clarified that providers and pharmacies are free to assist in beneficiary enrollment based on the beneficiary's needs, and beneficiary education. Furthermore, a Part D plan can use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans as long as the providers or pharmacies display printed information comparing the benefits of different Part D plans with whom they contract. The providers or pharmacies are not obligated to accept or display any comparative information regarding those Part D plans with which they do not contract.

Implications

In the past, pharmacists may have refrained from assisting

beneficiaries with plan selection or sign-up because they thought those activities were considered marketing by CMS and, therefore, not allowable. Pharmacists play an important role in education and enrollment assistance, and this role is recognized as allowable by CMS as long as no steering occurs toward a specific plan that benefits the pharmacy. The clarification of allowable marketing activities for pharmacists gives them the assurance that they can assist beneficiaries with plan selection or sign-up, based on beneficiaries' needs.

5. What if an Individual Enrolls in a Medicare Advantage Plan Based on Misleading or Incorrect Information?

CMS has established a special election period (SEP) to address situations where an individual has enrolled in a Medicare Advantage (MA) plan based on misleading or incorrect information provided by plan employees, agents, or brokers.[16] CMS will decide, on a case-by-case basis, whether the individual is eligible for a "Medicare Marketing Misrepresentation SEP," in which the beneficiary can select another MA plan, a Part D plan, or fee-for-service Medicare (Medicare A and B).

Implications

This guidance gives rapid recourse to beneficiaries who inadvertently signed up for an MA plan based on misleading information and who later find out that the plan is not right for them. Pharmacists can direct beneficiaries to the CMS help desk at 800.MEDICARE or to www.medicare.gov for assistance.

6. What Is the Member Transition Process for 2008?

There were minor changes to CMS guidance for 2008 regarding member transition to a new plan. CMS has devoted a significant portion of the Medicare Part D manual to this topic and requires plan sponsors to attest to their adherence to this policy on an annual basis. By developing standards for the transition process, CMS decreases the potential for member disruption and helps to facilitate a smooth transition of members from existing prescription coverage to a new plan.

A member transition process may apply to members new to a plan in any of the following scenarios:

1. Following the annual election period
2. Becoming a newly eligible Medicare beneficiary
3. Switching from one plan to another during the year
4. Residing in a long-term care (LTC) facility

The intent of the transition period is to prevent new members who are not yet familiar with their prescription formulary from being turned away from their pharmacy without medication on which they have been established. This transition period is a minimum of 90 days from the date when the beneficiary first becomes eligible in the new plan. Although the transition period is the first 90 days of eligibility, Part D plans are required only to provide up to a 30-day fill for ambulatory patients. That is because a member may have received a 90-day supply of medication prior to switching plans and may not need a refill until almost 90 days into the new plan. The 30-day temporary fill allows the member time to discuss formulary options with his or her physician or provide the time necessary to request a formulary exception.

LTC Transition Process

Based on the characteristics of LTC residents in which care is more intense due to complicated disease conditions and drug therapy regimens, special requirements have been instituted by CMS for transition of these members. As with the ambulatory patients, new LTC residents are also allowed a 90-day transition period; however, they are allowed multiple prescription fills for the entire 90-day transition period. These transition fills are allowed in a quantity up to a 31-day supply because many LTC pharmacies supply medications to nursing homes in blister packs based on a 31-day month. In addition to allowing multiple transition fills, plan sponsors are required to allow up to a 31-day emergency supply of medication for LTC residents who are outside of their initial 90-day period with a plan.[17] What constitutes an "emergency" is not specifically defined by CMS but is generally interpreted by the health care providers as any prescription that a patient needs to satisfy an immediate medical need, and the prescriber cannot be reached during normal business hours or after hours or weekends.

This provision is intended to prevent a disruption in initiation of therapy until the physician can be consulted about covered formulary options or the plan can be contacted to request an exception to the plan's formulary requirements. For example, an LTC facility contacts a physician because a resident has the symptoms of a urinary tract infection. The physician prescribes an antibiotic, and the LTC facility contacts its contracted pharmacy provider with the antibiotic prescription order. Once the pharmacy submits the claim, a rejection is received through the claims system that the antibiotic prescribed is non-formulary. At this point, the physician may no longer be available; also, the LTC pharmacy provider may have stated requirements or contractual requirements with the facility to deliver the acute medication within a specified amount of time, usually several hours. The emergency supply provision allows the pharmacy to receive a paid claim from the plan sponsor and provide the medication to the member expeditiously, preventing the LTC member from having a delay in delivery of an acute medication.

Medications Eligible for a Transition Fill

Medications that are eligible for a transition fill, regardless of patient setting, include drugs on the plan's formulary that have utilization management restrictions such as prior authorization, step therapy, or quantity limits, or those Part D-eligible medications that are considered non-formulary.

Process for a Transition Fill

The beneficiary is charged cost-sharing for the prescription for the transition supply. LIS beneficiaries may not be charged more than the statutory maximum copayment amounts for which they qualify during that benefit year. Non-LIS beneficiaries are charged the cost-share amount based on the previously approved benefit design. The copayment or coinsurance is the same amount as if the patient had received a formulary exception for the medication.

All plan sponsors are required to mail a transition fill notice via U.S. first-class mail to the beneficiary within 3 business days of receiving a transition fill. This notice by U.S. mail is necessary despite electronic messaging at point of dispensing to the pharmacist to indicate that a particular fill was allowed because the message may not always be conveyed to the patient. Patients may receive their medications and not realize that further action is required on their part prior to the next fill. The minimum requirements for the transition fill notice, as defined by CMS, are as follows:

1. Explanation of the temporary nature of the transition supply an enrollee has received
2. Instructions for working with the plan sponsor and the enrollee's prescriber to identify appropriate therapeutic alternatives that are on the plan's formulary
3. Explanation of the enrollee's right to request a formulary exception
4. Description of the procedures for requesting a formulary exception (e.g., provide a customer service number for the patient to contact to initiate the process)

Plans are encouraged to enhance the notification sent by U.S. mail to the beneficiary. The enhancement may include the reason for a transition fill (e.g., the drug requires prior authorization), appropriate formulary alternatives, and prior authorization forms to help facilitate the process for the member.

The requirements outlined above are minimum requirements, and plans may have more robust transition policies and procedures. Since transition policies and procedures vary and may influence plan choice by beneficiaries, CMS requires plan sponsors to make their transition policies available in plan enrollment materials and Web sites.

Implications

Pharmacists should ensure they are familiar with the specific transition policies for all plans for which they process claims. There are significant differences between transition policies for ambulatory versus institutionalized beneficiaries, including the emergency supply requirement for LTC beneficiaries and the multiple-fill allowance (i.e., the patient may receive up to 3 separate 31-day fills or a larger number of fills for shorter days supply up the first 90 days of the patient's eligibility for a beneficiary new to the plan). All patients, regardless of setting, should have a transition fill letter mailed to them within 3 business days of a transition fill. Pharmacists will undoubtedly receive questions regarding these letters and be asked for advice on how the patient should proceed.

7. How Should Part D Plans Use "Best Available Evidence" of LIS Status?

The best available evidence policy for LIS was developed by CMS in response to incorrect or lagging information of LIS status of members being passed on to the plan sponsors. The LIS status of a beneficiary is determined by either a state Medicaid agency or the SSA based on the information supplied to CMS on a monthly basis from the SSA and state Medicaid agencies. CMS then supplies this information to plan sponsors, which use this information to determine the appropriate cost-share amounts for LIS beneficiaries. If this information is not correct or is not supplied in a timely manner, some of the most vulnerable beneficiaries may be charged deductibles and copayments inappropriately and experience a lack of coverage of medication in the coverage gap or donut hole.

To assist beneficiaries in receiving the benefit to which they are entitled, CMS developed a best available evidence policy in 2006 and provided updates to this policy in 2007 for plans moving forward.[18] As the name implies, plans are to work from the best available evidence they have to determine a beneficiary's LIS status. Plans may act on evidence presented at the pharmacy to update a member's LIS status; however, CMS notes that this evidence should be followed up with additional information and considered only when it is necessary to address urgent situations.

The type of documentation that CMS considers appropriate to allow a LIS update by plan sponsors includes 1 or more of the following: (1) copy of the member's Medicaid card that includes the member's name and eligibility date; (2) report of contact, including the date a verification call was made to the state Medicaid agency and the name, title, and telephone number of the state staff person who verified the Medicaid status; (3) copy of a state document that confirms active Medicaid status; (4) printout from the state electronic enrollment file showing Medicaid status; (5) screen print from the state's Medicaid systems showing Medicaid status; or (6) other documentation provided by the state showing Medicaid status.

To establish that the beneficiary is institutionalized (e.g., LTC) and qualifies for a $0 cost-sharing level, the plan sponsor must furnish at least 1 of the following forms of proof: (1) remittance from the facility showing Medicaid payment for a full calendar month for that individual; (2) copy of a state document that confirms Medicaid payment to the facility for a full calendar month on behalf of the individual; or (3) screen print from the state's Medicaid systems showing that individual's institutional status based on at least a full calendar month stay for Medicaid payment purposes.

Once a plan has appropriate best available evidence, it may change the LIS status of a beneficiary for claims processing. On the basis of monthly file updates, CMS believes most of these

issues will resolve themselves without manual intervention. Plans are asked to wait 30 to 60 days to determine if the LIS is updated through the normal process. If there is no change, plans may make a LIS status correction request. Plan sponsors, or the business partner of plan sponsors, are required to maintain the records used to substantiate these requests for 10 years to satisfy the potential for government audits. Once a LIS determination has been made by CMS, the decision will be communicated to the plan's contact of record, in a format that is not explicit in the guidance.

Implications

Plan sponsors need to ensure that they have an internal best available evidence policy for LIS determination and are able to follow this procedure when appropriate evidence is provided at the pharmacy to lower a patient's cost-sharing at the point of dispensing. Although this situation can affect any LIS member regardless of patient setting, a large portion of LIS beneficiaries reside in the LTC setting. Unfortunately, LIS information is not always up to date or included in the eligibility information initially received by plan sponsors from CMS. LTC facilities will most likely act in good faith and not charge beneficiaries the higher copayments, anticipating an update to the LIS information.

8. How Has CMS Changed the Formulary Review Process?

Although changes related to formulary coverage requirements and the formulary review process are minimal for the 2008 benefit year, several are worth mentioning. First is the removal of the formulary key drug type (FKDT) inclusion criterion. The United States Pharmacopeia has developed a model formulary that contains therapeutic categories, pharmacologic classes, and FKDTs. For example, the renin inhibitor aliskiren, new to the U.S. market in March 2007, is in the therapeutic category of cardiovascular agents, the pharmacologic class of renin-angiotensin-aldosterone system inhibitors, and the FKDT of direct renin inhibitors. Plans in 2006 and 2007 were required to have at least 1 drug from each FKDT. Based on the FKDT requirement, plans would have been required to add aliskiren to their formularies. For 2008, CMS does not state that 1 drug from each of the USP formulary key drug types is required for a formulary to pass the approval process, but plan formularies will be compared against one another to identify outliers (defined as those plans that differ in FKDT inclusion from the majority of other Part D sponsors) that will be requested to make necessary enhancements to their formularies to receive approval. CMS also announced that the review process for formulary submissions in 2008 will be measured against an expanded list of treatment guidelines, but how this will be performed was not described in the guidance.

Another benchmark of comparison for formularies in 2008 will be the top 200 list of commonly prescribed medications in the Medicare/Medicaid population. This is a change from the previous comparison of 2006 and 2007 formularies against the top 100 list of commonly prescribed medications developed from the Medicare Discount Card program experience. This is an outlier test in which, again, CMS compares plans with their peers to determine if one plan formulary is substantially different from the majority of other plans. CMS does not provide a minimum number of top 200 drugs that must be covered to receive formulary approval but will develop expectations based on the averages determined by Part D sponsors in the marketplace.

Implications

Although there is no longer a requirement for at least 1 drug from each FKDT to be included in a plan's formulary, little has changed in the formulary review process for 2008. There are few unique FKDTs (e.g., long-acting opioid analgesics) that are not included on plan formularies. The ones that are not included on plan formularies will most likely be consistently excluded across the majority of plans because they offer little clinical advantage over existing medications to treat the same condition. For example, aliskiren will most likely be excluded from formularies because they will already contain multiple angiotensin receptor blockers and angiotensin-converting enzyme inhibitors, which, although not in the same FKDT, do share the same therapeutic category and pharmacologic class. In addition, the CMS list of top 200 commonly prescribed medications contains many drugs that are available as generics. Based on these benchmarks, few plans will be considered outliers by CMS and asked to make substantial changes to their formularies.

9. How Has the Definition of Specialty Tier Changed?

The definition of a specialty-tier medication changed in 2008: the cost of the medication must on average exceed $600 for a 1-month supply to qualify for inclusion on a formulary's specialty tier.[9] This is a $100 increase over the 2007 threshold of $500. Cost is the only criterion that must be met for inclusion on this drug formulary tier. Therefore, any medication, whether brand or generic, oral or injectable, may receive specialty-tier placement if a plan chooses to do so.

Implications

One aspect of specialty-tier designation is that plans are not required to provide copayment-tier exceptions for these medications and, therefore, do not have to honor a request by a beneficiary to receive the medication at a lower cost-sharing tier. The change in dollar threshold for inclusion on a plan's specialty tier will have minimal practical impact for 2008 because few drugs will end up falling off the specialty tier. Although a few medications may fall in the average price range of between $500 and $600 per month on average, the majority of medications that fall in this category easily exceed the new $600 minimum requirement limit. However, CMS is more closely scrutinizing which medications meet the qualifying criteria for specialty-tier

inclusion and is asking plans to justify their specialty drug designations.

In certain circumstances, one strength of a particular drug may exceed the $600 cost threshold, yet the lower strengths do not. Plans will be allowed to have a higher strength of that particular drug on a specialty tier, but not the lower strengths of the same medication (e.g., erythropoietin 40,000 units per mL meets the criteria whereas erythropoietin 3,000 units per mL does not). This disparity may cause provider and patient confusion over the specialty tier.

10. How Is a Specialty-tier Medication Different From a Specialty Drug?

It is important to make the distinction between a specialty-tier medication and a "specialty drug." What many in the health care industry refer to as a specialty drug, CMS refers to as a drug with limited distribution. CMS has taken the stance through previous guidance that plans may not restrict access to medications.[9] However, CMS recognizes that a limited distribution network may be necessary for certain drugs such as lenalidomide, which requires special patient, physician, and pharmacist education. In 2008, plans are required to identify the medications that have a limited distribution network on their formulary flat file submissions through the CMS Web-based Health Plan Management System (HPMS). CMS expects health plans to restrict to a limited distribution network only those drugs that require extraordinary intervention (not defined) in handling, provider coordination, or patient education that could not be provided by the regular pharmacy network.

Implications

Part D sponsors have traditionally managed high-cost medications, in part by permitting dispensing only through a limited distribution network. The limited distribution pharmacy network provides patient education and case management and ensures that medication protocols are followed; there may also be a cost advantage for plan sponsors. The new requirement in 2008 for plan sponsors to identify the medications that are limited to a special distribution network will most likely lead to a type of outlier test as seen in other aspects of the program. Plan sponsors are allowed to continue this arrangement, but the list of drugs CMS allows through a limited distribution network will likely be smaller than what is currently used by commercial (non-Medicare) health plans.

11. Is There a New Formulary Reference File?

In March 2006, plan sponsors were introduced to the formulary reference file (FRF). This medication list, produced by CMS, contains representative National Drug Code (NDC) numbers for each strength and dosage form of Part D medications. For example, there is only one NDC number to represent amoxicillin 500 mg capsules, not every NDC number for this medication that is commercially available. This reference file was developed in an attempt to reduce the number of unique NDC numbers that were submitted by plans for the drugs on their formularies. The FRF decreases the work load for plans and makes the review process more efficient for CMS. CMS has been clear in its guidance that inclusion on the reference list does not necessarily make a medication a Part D drug, nor does exclusion from the list mean that it is not a Part D drug.[19] All plans are required to make their own decisions as to the Part D status of medications. Although that may be the case, CMS will not accept submission of NDC numbers that are not found on the most current FRF.

CMS developed 2 different FRFs for 2007 and 2008, and each FRF pertains only to the respective year's formulary submissions. There are many NDC numbers on the 2007 FRF that are not on the 2008 version. That is because CMS has become more thorough in its review of FRF drugs to ensure they have an approved application on file with the U.S. Food and Drug Administration (FDA). Drugs that do not have an approved application on file with the FDA have been excluded from the 2008 FRF. Plans need to determine what impact these exclusions have, if any, on their members, as the formulary changes in 2008. Until recently, CMS required that as soon as a reference NDC number was removed from the FRF, it was to be removed from the formulary submissions and would not be accepted through the prescription drug event files for reimbursement from that point forward. Although member notification of removal from the formulary was encouraged, it was not required.[20]

DESI Drugs

In 2007, plans were challenged by the sudden change in Drug Efficacy Study Implementation (DESI) status of certain medications, such as the wound-healing ointment that has multiple formulations, including trypsin and balsam peru (e.g., Xenaderm). When these medications were reviewed by the FDA and determined to be less than effective DESI drugs, they no longer met the definition of a Part D medication. Plans often did not find this out until the reference file was updated. In addition, there was often a lag time before plan sponsors were able to operationalize a change in their adjudication systems. That resulted in plans paying for non-Part D drugs for a period of time, during which they did not receive reimbursement from CMS.

This situation changed on May 24, 2007. Since then, plans have been allowed to submit NDC numbers that were deleted from the FRF for 90 days after posting of the updated FRF. Although formulary submissions through the HPMS module are not allowed to have any NDC numbers that are not represented on the FRF, the plans' adjudication system may continue to process these claims and submit them for reimbursement. CMS expects that when a negative change occurs due to a Part D status change of a drug—that is, when a drug is removed from the formulary—plans will provide affected members 60 days notice before the change goes into effect.[19]

Implications

The FRF will continue to be a challenge for plan sponsors in 2008. Currently, the list is updated once a month. Some medications that are new to the market may be overlooked and may not be included for several monthly updates. Furthermore, inclusion on the list does not mean that a drug is a Part D drug, and exclusion does not mean that it is not a Part D drug. An FRF that is continuously updated (more than once a month) and that includes only drugs considered by CMS to be Part D drugs would be appreciated and well received by plan sponsors.

12. How Is Coverage Changing for Part D Vaccines?

The coverage of vaccines under Medicare Part D has been consistent since inception of the program; however, reimbursement for the administration component continues to evolve. In 2006, the guidance was clear that the administration of Medicare Part D-covered vaccines was not covered under the Part D or Part B benefit. The beneficiary was responsible for paying the administration fee, and because this fee fell outside of the Medicare benefit, none of it counted toward the patient's true out-of-pocket (TrOOP) expenses.[21] Whether the beneficiary had the standard benefit or was a LIS beneficiary who qualified f or extra help, he or she could be charged directly for the administration fee.

In 2007, the CMS position changed to allow the administration fee of a Part D vaccine to be covered under the Part B benefit.[22] This change came as a surprise to many plan sponsors, as guidance had been released in early December 2006 reiterating the policy that the administration fees fell outside of the Medicare benefit. In 2008, the policy has changed again to require the Part D plan sponsors to reimburse for both the vaccine and its administration.

Part D Vaccines

CMS has directed that starting in 2008, all Part D plans' formularies must contain all commercially available vaccines (unless they are already covered under Part B).[23] Medicare Part B covers pneumococcal pneumonia vaccine, influenza virus vaccine, hepatitis B vaccine for individuals at high or intermediate risk, and other vaccines (such as tetanus toxoid) when they are directly related to the treatment of an injury or direct exposure to a disease or condition. Part D covers zoster vaccine, human papillomavirus quadrivalent vaccine, and hepatitis B for beneficiaries who do not meet the intermediate- or high-risk coverage criteria. High-risk individuals include those who have end-stage renal disease, those with hemophilia who received Factor VIII or IX concentrates, clients of institutions for the mentally handicapped, persons who live in the same household as a hepatitis B virus carrier, homosexual men, and illicit injectable-drug abusers. Intermediate-risk groups include staff in institutions for the mentally handicapped and workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.[24]

Administration Fees

As of January 1, 2008, the administration fee associated with Medicare Part D-covered vaccines falls under the Part D benefit. This policy change is based on the fact that CMS views vaccines and their administration as having an "intrinsic relationship," citing that one cannot exist without the other.[23] The vaccine price, the dispensing fee, and the administration cost are collectively considered to be the vaccine price negotiated between the plan sponsor and the pharmacy. CMS expects that 1 claim will be submitted, whether received at an in-network pharmacy where the pharmacy dispenses and administers the vaccine or as an out-of-network claim where the physician supplies and administers the vaccine. Since the negotiated vaccine price contains all the components, beneficiaries are charged only 1 cost-share amount for the vaccine, the dispensing, and the administration. Whether the benefit design requires copayments or coinsurance, the entire price inclusive of all the components is applied to the specific coverage phase the patient is in.

Although CMS expects that vaccines and their administration are billed as 1 claim, they recognize that that may not be possible under all circumstances. There may be situations where a pharmacy dispenses the vaccination, but a physician or other qualified health care provider administers it. In this scenario, it is suggested that plan sponsors reimburse the pharmacy for the dispensing fee and the cost of the vaccine and reimburse the patient for the administration fee if he or she is billed for this service by the physician or other health care provider. CMS recognizes the potential "opportunity for both inappropriate and duplicate billing of administration fees." For that reason, CMS prefers the single-claim method and requires plan sponsors to perform their due diligence through claims analysis to prevent fraudulent billing when allowing separate billing of the vaccine and its administration. It is suggested that when the vaccine is billed separately from the administration, plans should verify this one-to-one relationship. If one component is seen without the other, the plan sponsor should reach out to the beneficiary to ensure that the beneficiary did receive the vaccine and did not forget to submit a paper claim for reimbursement of 1 of the components.

CMS expects the National Council for Prescription Drug Programs (NCPDP) to develop standardized claim submission fields that will allow submission of Health Insurance Portability and Accountability Act-compliant transactions for the vaccine and its administration as 1 claim. In addition, CMS is adding a vaccine administration field to the PDE for submission. Plans are required to include the vaccine and the administration, whether submitted on the same PDE file or separately, in the case of separate billing, to assist in identifying the one-to-one relationship.

Reimbursement of Vaccine Administration Fee

Plan sponsors are permitted some flexibility in various aspects of the administration fee reimbursement. For example, they are allowed to negotiate the administration fee with network

pharmacies. This fee varies from the Part B vaccine administration fee, which is more clearly defined. Plans also have the ability to determine whether they will have 1 flat dispensing fee or varying administration reimbursements that can vary by provider type or difficulty of administration. In addition, plans can have utilization management on vaccines to verify safe and appropriate use in line with the Advisory Committee on Immunization Practices guidelines.[9]

Implications

The inclusion of the administration fee in Part D is a service opportunity for pharmacists. CMS anticipates that "beneficiaries will consider receiving immunization of Part D vaccines in a pharmacy setting, given the real-time nature of the Part D benefit and the pharmacy's ability to bill the Part D sponsor without the beneficiary having to pay upfront for the vaccine and its administration, as he or she might in the physician's office."[15] Because of this new reimbursement structure for Part D vaccines, it may become standard practice for pharmacists to dispense and *administer* Part D vaccines such as zoster vaccine.

Looking Ahead

Medicare Part D is constantly evolving. The Children's Health and Medicare Protection Act of 2007 passed the U.S. House of Representatives and the U.S. Senate but was vetoed by President George W. Bush in October 2007.[25] The legislation proposed several beneficiary improvements to Medicare Part D, including (1) a SEP for beneficiaries in Part D plans that materially change their formulary to reduce coverage or increase cost-sharing for a drug that the beneficiary has been prescribed while enrolled in the plan, and (2) codification of the requirement that Part D plans cover all or substantially all drugs in 6 specific therapeutic classes of drugs (e.g., antiretrovirals, oral chemotherapy). The proposed legislation also allowed Part D coverage of benzodiazepines for the first time, simplified the application process for low-income beneficiaries, included costs incurred under AIDS Drug Assistance Programs and the Indian Health Service in TrOOP, and required consideration of factors such as pharmacy network and formulary when low-income beneficiaries are auto-assigned to a Part D plan. Although this legislation was vetoed, it is expected that similar changes may be addressed again in the 2008 legislative session. However, it is likely that any proposed changes to Medicare Part D during the 2008 election year will be administrative in nature.

Important Dates for 2008

- January 1-March 31: Special enrollment period for managed care plans.
- October 1: Plans begin marketing for 2009 plan year.
- Mid-October: 2009 plan data and enhanced plan finder available.
- October 31: Annual notice of change and *Medicare & You 2009* handbook must be in the mail to beneficiaries.
- November 15: Annual enrollment begins for 2009 plan year.
- December 8: Optimum date for early enrollment to ensure timely processing.
- December 31: Annual enrollment ends for 2009 plan year.

A pharmacist can find more assistance at the following sources:

- Call Medicare Pharmacists' Help Line: 866.835.7595
- Call 800.MEDICARE (800.633.4227)
- TTY users should call 877.486.2048
- Visit www.medicare.gov/contacts/static/allStateContacts.asp for a list of local senior health insurance program organizations.
- Call Social Security Administration: 800.772.1213.
- Read *Medicare & You* (CMS Pub. No. 10112).

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DISCLOSURES

No outside funding supported this research. Author Ronnie DePue served as principal author of the study. Study concept and design were contributed by DePue and author JoAnn Stubbings. Data collection and interpretation were primarily the work of DePue with input from Stubbings. Writing the manuscript was the work of DePue and Stubbings; its revision was the work of both authors.

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