SENIOR HEALTH NEWS

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THIS EDITION ENTIRELY ABOUT THE PROPOSED REGULATIONS FOR THE MEDICARE PRESCRIPTION DRUG PROGRAM

The proposed regulations for the Medicare Prescription Drug benefit were released in August 2004. These proposed regulations describe how the Medicare prescription drug benefit will look. We told you in our last issue of the Senior Health News that we would be publishing a special issue of the Senior Health News to let you know what the proposed regulations say. This issue will describe various parts of the proposed regulations and how they might impact you. We will be drafting and submitting written comments to the Medicare program on behalf of a number of our clients. We intend to publish those comments on our website as soon as possible. Others who wish to do so should know that the Medicare program is asking for input and would welcome your thoughts. The program does not begin until January 1, 2006. **However, comments must be receive by October 4, 2004.** To see the proposed regulations, you can go to www.cms.hhs.gov/regualtions or our website, www.phlp.org.

How will the prescription drug plan work?

Medicare beneficiaries will be able to sign up for a private Medicare approved prescription drug plan that will provide them with the Medicare prescription drug benefit. The benefit will not be provided by Medicare itself but by companies that Medicare contracts with. There is a standard benefit that the Center for Medicare and Medicaid Services has outlined in the regulations but plans can offer a different benefit as well.

What will the prescription drug benefit cover?

The basic prescription drug benefit will cover prescription drugs and insulin as well as supplies needed to take insulin. Which exact drugs are covered will depend on the plan that you pick. Plans may limit the drugs that are covered or have certain drugs that are preferred. Some plans may require that you have a prescription approved before they will cover it or may require that you try and fail on other medications before covering the one your doctor prescribed. If the drug is not covered, you will have to pay for it out of your own pocket.

The prescription drug plan will not cover any drugs that are covered by Medicare Part B, even if you don't have Medicare part B.

What will I have to pay for my prescription drugs?

The standard prescription drug benefit has many costs associated with it. You will have to pay a premium, which will depend on the plan. There will also be an annual deductible of approximately $250 for 2006. This means you

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will have to pay the first $250 worth of your covered drugs out of your own pocket. After that, you will pay 25% of the cost of your drugs until you have purchased $2250 worth of drugs. You do not have to pay the entire $2250. That is simply the total cost of the drugs paid for by you and your plan. After you have received $2250 in medications, then you will pay all of your drug expenses out of your own pocket, until you have spent $3600 on your medications. This is what is referred to as the "doughnut hole." After you have spent $3600 on your medications, then you will have coverage again. At this point, you will pay a co-pay of $2 each for a generic or preferred drug or $5 or 5% of a drug that is not generic or preferred, whichever amount is more. You should also know that these costs are not fixed and can change every year.

It is important to remember that the money that you spend on medications that are not covered by your plan will not count towards your total out of pocket costs and will not help you get to your deductible or get out of the doughnut hole once you are in it. Only drugs that are covered by your plan will count towards the costs described above.

Is the standard benefit the only benefit I can get?

No. The prescription drug plans can offer a different benefit package that might have different co-payments as long as the package offers about the same as the standard package. This may cause confusion.

Is there any help for Medicare beneficiaries with lower incomes?

Yes. People with lower incomes will be able to get a subsidy that will cover many of the costs described above, depending on their income. The breakdown is below:

Group	Full subsidy		Other subsidy
	People with · Income below 100% of poverty, or · Medical Assistance, or · SSI, or · Part B premium paid by the state	· People with income below 135% of poverty and, · Assets less than $6000 single, $9000 married	· Income below 150% of the poverty level and · Assets less than $10,000 single, $20,000 married
Premiums	100% of the premium is covered		Premium covered on a sliding scale
Deductibles	No deductible		$50
Co-pays	$1 generic or preferred drug, $3 any other drug. After reaching $3600 in drug costs, no co-pays	$2 generic or preferred drug, $5 any other drug. After reaching $3600 in drug costs, no co-pays	15% of the amount of the drug. After reaching $3600 in drug costs, co-pays are $2 generic or preferred, $5 any other drug
Doughnut hole	None - After reaching $3600 in drug costs, no co-pays		None - After reaching $3600 in drug costs, co-pays are $2 generic or preferred, $5 any other drug

The Pennsylvania Health Law Project
Presents
Information Sessions on the

Proposed Regulations for the Medicare Prescription Drug Benefit

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Pittsburgh	
Sessions Highlighting Disability Issues	Sessions Highlighting Senior Issues
Mon, Sept 13 @ 10am -12pm United Way Bldg Simmons Board Rm 1 Smithfield St Pittsburgh, PA *At this presentation, sign language interpreters available upon request*	Tue, Sept. 14 @ 1:30pm - 3:30pm Southwestern Pennsylvania Human Services Area Agency on Aging Eastgate 8 Monessan, PA
Thurs, Sept. 16 @ 1pm—3pm Cranberry Public Library 2525 Rochester Rd. Suite 300 Cranberry Twp, PA	Wed, Sept. 15 @ 10am—12pm Northland Public Library 300 Cumberland Rd. Pittsburgh, PA
Philadelphia– One Session Only!	
Thursday, Sept 16 @ 10am – 12pm Philadelphia Bar Association 1101 Market St., 11th flr Philadelphia	
Harrisburg– One Session Only!	
Monday, Sept 20 @ 10am – 12pm Pennsylvania Medical Society Bldg 777 East Park Dr. Harrisburg, PA	

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Enrollment into the Medicare Prescription Drug Plans

Persons who are eligible for or enrolled in Medicare Part A and/or Part B can first sign up for a Part D prescription drug plan beginning in November 2005. Consumers who receive full Medicaid benefits in addition to Medicare (called "dual eligibles") **will lose their drug coverage under Medicaid on January 1, 2006 and will have to join a Part D plan in advance to obtain coverage for their prescription drugs**.

Enrollment into Medicare Part D Plans:

Medicare will approve Prescription Drug Plans and Medicare Advantage Plans (formerly called Medicare + Choice) most typically Medicare HMO's to provide prescription drug coverage to Medicare consumers. Consumers who are enrolled in a Medicare Advantage plan that offers drug coverage must obtain drug coverage through that plan. Other Medicare consumers can enroll in any Prescription Drug Plan in their service area. Each Prescription Drug Plan is required to enroll any person eligible for Part D who wants to enroll.

Those who want to enroll in a Part D plan must apply directly to the entity offering the plan they want to join. The initial enrollment period is November 15, 2005 to May 15, 2006. Consumers who are full dual eligibles and who fail to enroll with a Part D plan by May 15, 2006 will be randomly auto-enrolled into a plan. This is problematic for several reasons. One reason is that these persons will lose drug coverage through Medical Assistance on January 1, 2006. As a result, they could be without drug coverage for as many as long as 5 months until they are auto-enrolled into a plan. Another problem is that these dual eligibles may be enrolled into a plan that does not cover all the drugs that the individual is currently taking. Education of dual eligibles will also be extremely important to ensure that they understand that they will lose their drug coverage under Medicaid and that they must enroll with a Part D plan to avoid a gap in coverage.

With few exceptions, once consumers enroll in a Medicare Part D plan, they are locked-in to their plan choice for a year. However, dual eligibles qualify for a special election period and they can disenroll from one Part D plan and enroll in another plan in their area at any time.

One area of particular concern is that the proposed regulations would give Part D plans the option to disenroll a member for "disruptive behavior" or "misrepresentation about creditable coverage". The standards are vague for what would be considered "disruptive behavior". Advocates are concerned that persons with certain disabilities or conditions may be unfairly penalized for behavior they cannot control and that the health plan may consider "disruptive". In addition, the complexity of the program will

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Enrollment continued...

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lead to a great deal of confusion for consumers. Consumers may unknowingly give inaccurate information that could then lead to their disenrollment for "misrepresenting" their coverage. This also has implications for future coverage because Part D plans may refuse to reenroll consumers who were previously disenrolled for these reasons.

Late Enrollment Penalty

Consumers who are eligible for Part D but who choose to not enroll in a Part D plan during the enrollment period will incur a substantial penalty if they enroll in a Part D plan at a later time unless they had creditable coverage (this is defined as coverage that is actuarially equivalent to the standard benefit coverage under Part D) . Specifically, the consumer will have to pay a higher premium for their Part D coverage forever.

Dual eligible consumers who are not full dual eligibles but still receive some subsidy are not exempt from this late penalty. The amount of the late enrollment penalty will be lower for these individuals, but they will still be required to pay. If this provision appears in the final regulations, this is an area where education is extremely important so that dual eligibles will not incur the late enrollment penalty and encounter further financial hardship given their limited incomes.

Enrollment Into the Low-Income Subsidy

Consumers with incomes less than 150% of FPL are eligible for a low-income subsidy. To obtain the subsidy, consumers must file a separate application (in addition to the one filed with the Part D plan). Consumers can apply for this subsidy either through either the County Assistance Office (CAO) or the Social Security Office. Eligibility will be determined by the state, however, if a person is denied the subsidy and wants to appeal that decision, the appeal process available will be either the DPW Fair Hearing process (if they applied to the CAO) or any appeal process established by the SSA Commissioner (if they applied to the Social Security Office).

Consumers who apply through the CAO will be screened for eligibility for full Medicaid as well as the Medicare buy-in programs. Consumers who are already enrolled in Medicaid will be deemed eligible for the full subsidy; however, there is no provision to auto-enroll these individuals into the subsidy.

An individual consumer or their personal representative can complete the application for the low-income subsidy. Whoever completes the application must certify, under penalty of perjury, that the information on the application is correct. The proposed regulations are not clear as to the definition of personal representative. This could have serious implications for advocates who assist consumers in applying for the low-income subsidies if any information provided turns out to be incorrect.

Accessing prescription drug benefits

Once a consumer is enrolled into a Part D plan, they may face a number of barriers to actually obtaining the medication they need. These barriers are discussed below:

Not all types of drugs covered by Part D
Medicare Part D will provide coverage for FDA approved drugs, biological products, and insulin and its associated medical supplies. Medicare Part D **will not** cover:

- any drugs that are currently excluded from Medicaid coverage;
- Over the Counter (OTC) medications; and
- Drugs covered by Medicare Parts A and B (regardless of whether a consumer is Part A or Part B).

The State Medicaid program may be able to provide wrap around coverage for dual eligibles for drugs that are not considered covered Part D drugs (for example, Medicaid can cover OTC medications for dual eligible consumers). However, this could still leave Medicare consumers without coverage for some types of medications they currently take.

Each plan will have a different formulary or list of drugs that it covers

The proposed regulations impose very few requirements for the development of each plan's formulary. Among the requirements are:

1. Each plan must have a pharmacy and therapeutic (P&T) committee to develop its formulary. The P&T committee is required to have a majority of members who are practicing physicians and/or practicing pharmacists, and at least one of these members is required to be an expert in the care of the elderly and persons with disabilities. Plans are "encouraged" to have committee members representing various clinical specialties. To ensure that plans develop formularies that provide adequate coverage to the entire Medicare population (both elderly consumers as well as persons with disabilities), it seems most logical that the P&T committee requirements should be changed to include an expert in the care of older adults as well as a number of experts specializing in the various areas of care for persons with disabilities (including both physical health and mental health experts).

2. Each plan's formulary must cover at least two drugs from each therapeutic category/class of drugs. While the US Pharmacopoeia has developed guidance on what therapeutic category/classes of drugs the health plans should cover in their formulary, the health plan is free to develop its own classification system. That means that each health plan could have its own list of categories/classes of drugs that it covers and each health plan will have a different list of drugs it covers within each of these categories. This will put a great deal of burden on the consumer to compare and contrast different Part D plans' formularies if they want to make an informed decision about which plan to join. In addition, it is not clear whether each plan's complete formulary will be available to eligible Part D enrollees in printed form before they enroll.

Allowing each plan to have a different classification system and/or different formulary also adds to the confusion and complexity for providers when prescribing medications for Part D eligible individuals as well as for pharmacists when filling these prescriptions.

The proposed regulations set forth an exception process through which consumers can request non-formulary drugs, but there are problems caused by lack of clear standards and long timeframes for the process. See the

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article on p. 8 regarding Appeal Rights.

Pharmacy Access Standards:

The proposed regulations outline pharmacy access provisions that are based on mileage. For example, for urban areas, at least 90% of the consumers served by the plan must live within 2 miles of a network pharmacy). This pharmacy access standard differs from the standard used by Medicaid HealthChoices. HealthChoices uses travel time rather than mileage because traveling in an urban area can take a long time even if consumers are only traveling short distances.

Medicare Part D plans may also provide access to network mail order pharmacies provided the plan meets the network access requirements for retail pharmacies (as described above). In addition, the proposed regulations state that plans must allow consumers to get an extended supply of medication (45/60/90-day as opposed to 30-day supply) at the retail pharmacy rather than through a mail order pharmacy. However, this extended supply is likely to cost more at a retail pharmacy and the consumer will be responsible for any price differential.

Finally, Part D plans are required to ensure consumers have adequate access to covered Part D drugs at out-of-network pharmacies in situations where they cannot get to a network pharmacy. Consumers using an out-of-network pharmacy will be responsible for paying any difference in price from what the out-of-network pharmacy charges and what the health plan would pay for the drug at a network pharmacy.

What does "proposed regulations" mean?

The regulations described in this newsletter are proposed regulations. This means that they are not the actual rules for the Medicare Part D Prescription Drug benefit; they are only the rules that the Center for Medicare and Medicaid Services (CMS), the agency that runs Medicare, is thinking about applying to the program. Before CMS can make final rules on the prescription drug benefit, it must first allow the public to comment on the proposed rules. Anyone who would like to make comments about the proposed regulations must get their comments to CMS by October 4, 2004. PHLP's comments will be posted on our website www.phlp.org no later than September 27th.

Comments can be sent several ways. You can send them electronically by going to www.cms.hhs.gov/regulations/ecomments. You can also mail them to CMS. If you mail comments, you should send one original copy and two copies and leave enough time for the comments to arrive by October 4. Comments received after October 4, 2004 will not be considered by CMS. The address to mail comments is: Centers for Medicare and Medicaid Services, Department of Health and Human Services, Attention: CMS- 4068-P, P.O. Box 8014, Baltimore, MD 21244-8014. You can also hand deliver your comments. You should call CMS at 410-786-7197 to arrange this. You cannot fax your comments to CMS.

CMS asks for public comment in many sections of the proposed regulations. Many of the sections are not very specific and CMS wants to hear what the public thinks. You can find the regulations on the CMS website, www.cms.gov/regulations or from our website, www.phlp.org. After the public comment period ends, CMS will consider the comments made on the proposed regulations. It expects to publish final regulations on the prescription drug benefit in the spring of 2005. The final regulations will govern how the drug benefit works.

Appealing under Medicare Part D

The proposed Part D regulations outline the various processes available to consumers who wish to challenge a Part D Plan's coverage of a certain drug or to dispute certain actions taken by a plan. The following three processes are described in more detail in the following sections:

- ***Exceptions process***—allows consumers to request a non-formulary drug and to request an exception to the Plan's tiered cost-sharing structure.
- ***Appeals process***—allows consumers to dispute "coverage determinations" made by a Plan about the benefits it covers or the amount a consumer must pay.
- ***Grievance Process***—allows consumers to dispute a Part D Plan's operations, activities or behavior.

Exceptions Processes

To request an exception to a Part D Plan's tiered cost-sharing structure (i.e. to obtain coverage for a "non-preferred" drug), the consumer must show, at a minimum:

- that the preferred formulary drug would not be as effective for the enrollee as the drug requested; and/or
- that the preferred formulary drug may have adverse side effects for the enrollee

Similarly, to request an exception to the formulary and seek coverage of a non-formulary drug (or to exceed a dose restriction), a consumer must show that a non-formulary drug is medically necessary because:

- no drug on the formulary is an acceptable clinical alternative:
- the formulary alternatives have been ineffective in treating the consumer, or, based on clinical/medical/scientific evidence, are likely to be ineffective; or
- the number of doses available under a dose restriction has been ineffective or is likely to be ineffective (based on clinical/medical/scientific evidence)

Even if a consumer meets the established criteria shown above, the Plan need not provide coverage for the medication. The plan is allowed to deny the request as long as it maintains an exception process that includes the consideration of certain criteria when making its determination. This lack of a clear standard that requires coverage of the requested drug when certain established criteria are met is very problematic. Applying a uniform standard, such as the medical necessity standard used in Pennsylvania's HealthChoices program, would provide more clarity to consumers and prescribing doctors and offer more equitable access to needed medications across the Plans.

In addition, having CMS develop uniform exception criteria for a specific class(es) of drugs (i.e. mental health medications) would be an additional protection for vulnerable consumers who often rely on medications to live. Finally, guaranteeing that consumers be able to continue to get a medication at a given price for the remainder of the year in the event of a mid-year change to the tiering structure would seem a minimal yet extremely important consumer protection that must be included in the regulations.

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Appeals Process

The proposed regulations allow consumers to appeal a Plan's denial of an exception request or any other coverage determination. The appeals process CMS proposes is the same as the one in place for Medicare +Choice (the Medicare HMOs). This current process is lengthy and complicated. The timeframes vary between an initial determination and redetermination by the Plan before a consumer can seek review by an Independent Review Entity (IRE). If the consumer is still unsatisfied and the amount in controversy is at least $100, he/she can pursue their appeal further to an Administrative Law Judge, the Medicare Appeals Council, and ultimately to federal district court.

The proposed appeals process poses many barriers for consumers. Every timeframe for decision-making can be extended by the plan (even an expedited appeal!). If a Plan fails to issue a timely decision, even with an extension, it is considered a denial rather than an automatic approval. If a consumer is disputing a Plan's formulary change which no longer covers a medication the consumer had been using, the consumer is not entitled to continue receiving the benefit pending the outcome of the appeal. It is crucial that the final regulations provide at least minimal consumer protections including:

- ????Consumers should be guaranteed the right to continue to receive an ongoing medication that the Plan is removing from its formulary (or restricting in some other way) pending the final outcome of their appeal;
- ????A Plan's failure to issue a decision within the timeframes provided should be deemed an approval.

Grievances

Any consumer complaint or dispute regarding the Plan's operations, delays in providing or approving coverage (unless the delay adversely affects the consumer's health), or the quality of its services, is to be handled through the Plan's grievance process. The proposed regulations regarding grievances are skeletal. Plans are given a great deal of discretion over how they will decide grievances, how the decision will be communicated to the consumer and how grievances are tracked or used for quality improvement.

In its comments to the proposed regulations, CMS indicates it is looking for guidance and suggestions regarding the grievance process-especially current state consumer protections that should be incorporated. In Pennsylvania, under Act 68 (one of the state laws governing HMOs) consumers have important rights that should be included in these regulations including:

- a right to a written decision within 30 days;
- a right to a decision from someone not previously involved in the dispute; and
- an ability to pursue a grievance further before an impartial entity outside of the Plan
- a right to dispute the plan's decision to characterize or recharacterize the consumer's appeal or grievance.

Strengthening the Appeal and Grievance sections of the proposed rules is critical to assuring consumers will be able to access prescription medications they medically need under the new program. As a result, consumers, providers and advocates will want to carefully scrutinize the appeal and grievance provisions and provide comments to CMS that reflect their concerns and offer recommendations to improve Part D Plan procedures.

What is the Pennsylvania Health Law Project?

The Pennsylvania Health Law Project (PHLP) is a non-profit public interest law firm that provides free legal services, community education, and advocacy for lower-income persons, seniors, and persons with disabilities who are having trouble accessing healthcare coverage or services. PHLP staff provide direct assistance to consumers, presentations to the community, trainings for advocates, and informational materials for anyone. Check out our website including our other free newsletters at www.phlp.org!

Consumers who are having trouble getting eligible for programs or getting services once they are in programs may obtain free assistance by calling the Pennsylvania Health Law Project Helpline toll-free at (800)274-3258.

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