Argus Comments for Standardized Pharmacy Notice (CMS-10147)

July 5, 2011

1. Type of Information Collection Request

Revision of a currently approved collection; Title of Information Collection: Standardized Pharmacy Notice: Your Prescription Cannot be Filled (f/k/a Medicare Prescription Drug Coverage and Your Rights) Use: This is a request for approval of changes to a currently approved collection under 42 CFR 423.562(a)(3). This regulatory provision has recently been modified to eliminate the previously available option of posting the standardized notice at the pharmacy. Revised 423.562(a)(3) and an associated regulatory provision at § 423.128(b)(7)(iii) require the pharmacy to provide the Part D enrollee with a printed copy of this standardized notice if the prescription cannot be filled.

The purpose of this notice is to provide enrollees with information about how to contact their Part D plans to request a coverage determination, including a request for an exception to the Part D plan's formulary. The notice reminds enrollees about certain rights and protections related to their Medicare prescription drug benefits, including the right to receive a written explanation from the drug plan about why a prescription drug is not covered.

A Part D plan sponsor's network pharmacies are in the best position to notify enrollees about how to contact their Part D plan if the prescription cannot be filled.

As noted in a final rule published April 15, 2011 (76 FR 21432), the option of posting this notice at the pharmacy has been eliminated. If a prescription cannot be filled, the pharmacy must provide the enrollee with a printed copy of this notice. Form Number: CMS–10147 (OCN: 0938–0975) Frequency: Yearly; Affected Public: Private Sector—Business or other For-profits; Number of Respondents: 42,000; Number of Responses: 37,087,402; Total Annual Hours: 617,876. (For policy questions regarding this collection, contact Kathryn McCann Smith at 410–786–7623. For all other issues call (410) 786–1326.)

Argus Comment/Question:

There may be situations where the beneficiaries' drug was covered by a secondary payer or processed under a discount card. In this instance the actual prescription will be filled and the claim would not be in a denied status.

NCPDP recently approved the use of the Part D BIN/PCN where payment by another source is made even if the Part D plan has not made payment. Specific examples include

1) The drug was submitted to a Part D BIN/PCN where the processor co-administers a secondary benefit such as an SPAP all in one claim submission. In this instance the Part D plan may not have paid or covered the drug, but the SPAP will. The pharmacy will receive a paid response and see a benefit stage qualifier = 50 on these claims. The member has received coverage for the drug albeit by the secondary and not the Part D Plan.
2) The drug was submitted to a Part D BIN/PCN where the processor offers a negotiated rate (usually referred to as a discount card) on drugs not covered by the Part D Plan. In this instance the pharmacy will see a paid response, 100% coinsurance of the negotiated rate and a benefit stage qualifier = 70.

Both of these examples may result in a filled claim that did not have any coverage by the Part D Plan. In these instances the plan would return a new Approved Message Code = 018 - Provide Beneficiary with CMS Notice of Appeal Rights. The definition is "Claim for a Part D drug submitted to the plan's Medicare D BIN/PCN is not covered by the Part D plan and is outside the Part D

transitional fill coverage period, but is paid under the plan's co-administered benefit or plan-sponsored negotiated price to the beneficiary. In this situation the member should be provided the Medicare Part D Appeal and Grievance Notice."
Based on these two scenarios we respectfully request that CMS modify the Title of the notice and all corresponding materials to reflect "Your prescription was not covered by your Part D Plan". We would also recommend some clarifying language in the notice to indicate that it is possible that the drug was covered by a payer supplemental to Part D or provided a negotiated rate.

Also, please take out any reference to prescription **rejections** as the scenarios above would not result in a rejected claim.

We also feel that Long Term Care claims should be exempt from printing and providing the notice to the beneficiary since LTC pharmacies do not have direct contact with the beneficiary.

August 1, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulatory Development
Attention: CMS-10147
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

[Submitted online at: www.regulations.gov]

Re: Docket No. CMS–10147. CMS Information Collection Request: Standardized Pharmacy Notice – Your Prescription Cannot be Filled

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed information collection request, *Your Prescription Cannot be Filled (f/k/a Medicare Prescription Drug Coverage and Your Rights)*, published May 31, 2011 (76 FR 31338). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. Our comments reflect the views of pharmacists practicing across the spectrum of health and patient care settings.

APhA appreciates the efforts of CMS to modify the current standardized pharmacy notice (Form Number – CMS 10147) to comply with the recently adopted Final Rule *Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes* (76 FR 21432). As indicated in the Final Rule, 42 CFR 423.562(a)(3) was amended to remove the option for pharmacies to post notices instructing Medicare Part D enrollees how to contact their plans to obtain a coverage determination or request an exception if the patient disagree with the plan's coverage denial decision and relayed by the pharmacist. The Final Rule instead requires pharmacists to provide written notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception.

While we understand that CMS must implement the Final Rule pursuant to pharmacist distribution of the notice, we are concerned with the potential for administrative burden and cost shift to pharmacy to

implement the requirement. Furthermore, given that prescription claims denial information that pharmacists provide to patients is based on real-time, electronic prescription claims adjudication messaging received directly from the Part D plan, we encourage CMS to explore ways to require plans to directly contact their enrollees to provide them with the denial information and instructions for pursuing coverage determination/exceptions. It would be beneficial for Medicare patients to receive information directly from the plan making the initial coverage determination and for what reason in order to have timely information available to address the claim issue.

As CMS finalizes the standardized notice, APhA recommends that CMS consider the following recommendations to improve the document and ensure patients receive the information that is most helpful for them to access needed medications:

- Clarify distribution expectations for the form regarding need to dispense every time any applicable real-time electronic claim denial is issued regardless of efforts to resolve the issue (i.e. dialogue between pharmacists and prescriber to potentially dispense a different medication that is covered), or only when the patient needs to initiate the coverage determination and exceptions process.
- Clarify distribution options for pharmacies that may have the technology to create an electronic, patient-customized, computer-generated print-out of the standardized notice. The distribution options should not be restricted to paper-only as systems move to utilization of electronic health information.
- Clarify if the patient has an option for how they wish to receive the information (paper or electronic message).
- Provide additional guidance on distribution if the patient does not return to or contact the pharmacy, then compliance with the notice distribution should be negated.
- Ensure that a claim denial message clearly indicates that the patient is on a Medicare Part D plan, not a private plan with the same insurer.
- Ensure that improvements continue in claims messaging so that specific information as to why a claim was denied is included in the electronic message facilitated through NCPDP standards in addition to the steps that need to be taken to resolve the claim or what drug would be covered.
- Ensure that Part D patients receive general coverage determination options and information from their plan (i.e. in a yearly welcome packet or something similar) to help increase enrollee awareness of steps to address potential coverage issues.
- Consider ways in which the plan could cover the costs of distribution as the proposal is a cost shift to pharmacy.
- Clarify mail-order pharmacy requirements to distribute the notice.
- Consider revising the title of the document from “Notice: Your Prescription Cannot be Filled” to <u>“Notice: Your Insurance Did Not Pay for Your Prescription”</u> or something similar so as not to suggest that pharmacy/pharmacist made the decision.
- Clarify requirements related to distribution of notices in foreign languages.
- Continue to evaluate the readability and literacy level of the notice.

Conclusion

As CMS finalizes provisions requiring pharmacist to distribute the standardized notice, we encourage you to consider the previous recommendations. Pharmacists are committed to the needs of patients but are concerned with the potential administrative burden and cost shift to pharmacy. We also urge CMS to consider ways to ensure that plans are also providing this information to patients.

Thank you for the opportunity to provide comments on the standardized pharmacy notice. We look forward to continuing to work with CMS on this important issue. If you have any questions or require additional information, please contact Marcie Bough, Senior Director of Government Affairs at mbough@aphanet.org or by phone at (202) 429-7538.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

TM/mb

cc: Brian Gallagher, BSPharm, JD, Senior Vice President, Government Affairs
Marcie Bough, PharmD, Senior Director, Government Affairs

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
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August 1, 2011

The Centers for Medicare and Medicaid Services

Attention: Kathryn McCann Smith

Re: Form Number CMS-10147 (OCN-0938-0975)

Filed at wwww.regulations.gov

Dear Ms. Smith:

The Blue Cross and Blue Shield Association would like to provide comment on the new standardized form, "Your Prescription Cannot be Filled," which we understand is going through the review process under the Paperwork Reduction Act.

BCBSA plans participate in the Medicare Advantage and Part D programs and therefore have an interest in the use and distribution of this form as our Plans and their delegated entities provide Rx benefits to millions of Medicare beneficiaries today in these two programs.

BCBSA supports and welcomes the CMS change that instructs beneficiaries to request a coverage determination by contacting the plan directly via either the toll-free number on the membership card or the plan's website instead of referring the beneficiary to the plan's benefits booklet and 1-800-Medicare. This revised instruction provides plans with greater opportunities to engage more fully with their beneficiaries through the plan's internal appeal process. Likewise, this change in instruction will lead to earlier plan intervention, which may result in a decrease in the potential number of CTM cases sent to CMS for review.

Change in Title of Notice

In the crosswalk which accompanied the Federal Register announcement, CMS indicates that the title of the pharmacy notice is being modified to read, "Notice: Your Prescription Cannot be Filled" in order to clearly convey to the enrollee that he or she is receiving the notice because the pharmacy cannot fill the enrollee's prescription and to streamline the text related to when an enrollee has the right to request a coverage determination from the Part D plan. As written, the proposed title may incorrectly lead beneficiaries to conclude that the plan does not cover the particular prescription when some other basis is the cause for the prescription not being filled. For this reason, BCBSA suggests that CMS retain the current title, "Medicare Prescription Drug Coverage and Your Rights".

We support the contents of this notice. We also seek one clarification. This form should be assigned to the applicable retail pharmacy staff to provide to the applicable member and Part D sponsors or Medicare Advantage Health Plans should not under any circumstance have an obligation to provide this for to a member who is unable to fill their prescription at the retail site.

There appears to be some CMS staff telling Health Plans that if the pharmacy is unable to perform this function, then the distribution is then delegated to either the Part D sponsor or the Medicare Advantage Plan.

Therefore we ask that all subsequent instructions associated with this form clearly state the obligation of network pharmacies and their staffs to provide this form as needed.

Questions on this comment may be directed to my office at Jane.Galvin@bcbsa.com.

Sincerely,

Jane Galvin
Managing Director
Regulatory Affairs

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July 29, 2011

Submitted Electronically at regulations.gov

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Division of Regulations Development
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Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to CMS-10147: Standardized Pharmacy Notice
Document ID CMS-2011-0112-0001

To Whom It May Concern:

The undersigned organizations are a coalition of consumer advocates with extensive experience assisting beneficiaries who confront pharmacy access problems in both the Medicare and Medicaid programs. We submit these comments to the above-referenced pharmacy notice.

General Comment re: Individualized Notices

We recognize that this notice follows the final regulations set out in CMS-4144-F, issued April 15, 2011, that require pharmacies to give a general notice that Medicare beneficiaries can contact their drug plans if they are told at the pharmacy that coverage will not be provided. Our organizations continue to assert, however, that individually-tailored notices provided at the point of sale that explain why coverage was denied are legally required. Until that requirement is met, though, we

believe that this standardized notice is an important interim step, and that the provision of a generalized notice to each individual is an improvement upon the current requirement that information merely be posted in the pharmacy.

We appreciate the opportunity to provide the following specific comments to the draft notice, organized by section.

First Section – Your Medicare Rights

The notice states that a beneficiary has the right to request a coverage determination from his or her "Medicare drug plan." The phrase "or Medicare health plan" should be added to reflect that some people get their drug coverage through Medicare Advantage-Prescription Drug Plans (MA-PDs).

Among the reasons listed for which a beneficiary can request a coverage determination, the second bullet states that "A coverage rule (such as prior authorization or a quantity limit) should not apply to you for medical reasons." The phrase "or if you have already met the coverage rule" should be added to this bullet so that it reads "A coverage rule (...) should not apply to you for medical reasons or if you have already met the coverage rule."

We appreciate that the third bullet addresses a situation in which an individual might request an exception to tiered cost-sharing if they "need a non-preferred drug" and the individual wants "the plan to cover the drug at the preferred drug price." In order to ensure that a beneficiary is aware of the right to make such a request, we suggest that instructions given to pharmacists about this notice include clear language about tiering exception scenarios. Currently, both the title of the notice "Your Prescription Cannot be Filled" and the accompanying Form Instructions for the notice which states that it must be used "[i]f the pharmacy cannot fill the enrollee's prescription" do not adequately account for situations in which a beneficiary has a right to request a tiering exception. In other words, a prescription might be able to be filled, but an individual might not be able to afford it, or believe s/he should pay a preferred price. For example, if a beneficiary expresses to the pharmacist that s/he cannot afford a prescribed non-preferred drug, or asks about alternatives, instructions to pharmacists (and corresponding CMS manual provisions governing plan sponsors) should include this situation as one requiring distribution of this notice.

In addition, as proposed by the MAPRx Coalition in separate comments, we recommend that the form include a brief checklist of possible reasons for denial. The pharmacist should then be required to check the applicable reason so that the beneficiary receiving the notice would know exactly why the plan has refused to cover the prescribed drug. This checklist would include as an option a checkbox entitled "Other" along with a space for the pharmacist to indicate the reason for the denial. Although such a checklist would not contain all of the information

necessary to properly exercise one's appeal rights or other options under plan rules, such as a list of alternative drugs that are on the plan's formulary, a checklist would certainly aid an individual in understanding why a drug has been denied. As suggested by MAPRx, the list could be similar to this example:

> Your Medicare Part D prescription drug plan has denied coverage for the following reason:
>
> _____ Prior Approval Required by Plan
>
> _____ Exceeds Quantity Limits
>
> _____ Step Therapy Required
>
> _____ Other
> Reason provided by plan:
> _____

Second Section – What you need to do

Similar to a comment above, the reference to contacting "your Medicare drug plan" should be expanded to include "or Medicare health plan" to account for individuals enrolled in MA-PDs.

We believe that the list of items an individual should have ready when they contact their health plan is helpful. We suggest that item number 2 about requesting exceptions be moved to the end of the list since not all enrollees will be requesting exceptions.

We suggest that a fifth bullet be added to this list to reflect an individual's right to request an expedited coverage determination. For example, language similar to the following could be used: "5. Whether you need the drug plan to make an expedited (faster than usual) decision on your coverage determination or exception request if your health is threatened (you can ask your doctor to support your request for a faster decision)."

In the last paragraph, time frames within which a plan must provide an enrollee with a written decision should be included, both for standard and expedited appeals.

Language Access

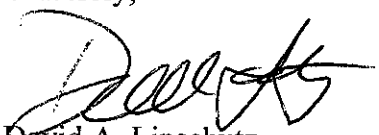
Because the notice is both very important and short, we strongly recommend that CMS provide plans with model translations in 10-15 languages so that pharmacies serving individuals with needs for language services can have appropriate information available. Since the document is only one page in length, we also

recommend printing it in English on one side and Spanish on the other as a simple way to address the needs of the largest group of limited English proficient beneficiaries.

If multiple translations will not be immediately available, we urge that pharmacies be told to also include a one-page insert with tag lines in multiple languages telling recipients that they can get interpreter assistance in understanding the document by calling the plan's customer service number. We understand that CMS is in the process of developing this insert for inclusion with marketing materials and urge that it be used at the pharmacy as well.

We appreciate the opportunity to provide these comments. Thank you for your time and attention.

Sincerely,



David A. Lipschutz
Center for Medicare Advocacy

On behalf of:

Families USA
Tennessee Justice Center
Medicare Rights Center
National Senior Citizens Law Center
National Health Law Program

Please find the attached comments that are being submitted on behalf of CVS Caremark / CVS pharmacy, SilverScript Insurance Company (S5601), RxAmerica Part D Plans –Accendo (S5644) and Community CCRx (S5803,S5825). These comments are with respect to Form Number: CMS–10147 (OCN: 0938–0975). As required by section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) published revisions of the currently approved collection; "Standardized Pharmacy Notice" for public comment. The title of the Standardized Pharmacy Notice has been changed from "Medicare Prescription Drug Coverage and Your Rights" to "Your Prescription Cannot be Filled." Request for approval of changes is for the currently approved collection under 42 CFR § 423.562(a)(3). This regulatory provision has recently been modified to eliminate the previously available option of posting the standardized notice at the pharmacy. Revised § 423.562(a)(3) and an associated regulatory provision at § 423.128(b)(7)(iii) requires the pharmacy to provide the Part D enrollee with a printed copy of this standardized notice if the prescription cannot be filled.

The Necessity and Utility of the Proposed Information Collection for the Proper Performance of the Agency's Functions

Per the 2012 Medicare D Call Letter, Part D sponsors are required to modify their electronic transactions to pharmacies so that they can transmit codes instructing pharmacies to distribute notices at the point of sale (POS). Pharmacies and pharmacy benefit managers (PBMs) are required to program their systems to relay the message at the pharmacy to distribute the POS pharmacy notice that instructs the enrollee to contact the plan sponsor to request a coverage determination.

The CMS regulation does not clearly state that the Appeal Notice needs to be provided to the Medicare D beneficiary only when beneficiary walks away from the pharmacy without the medication authorized by their physician, and not when the reject code is resolved. Without this clarification, it may be interpreted that the pharmacy must provide the Appeal Notice whenever the Part D processor returns the designated reject code (569 – Provide Beneficiary with CMS Notice of Appeal Rights) regardless of whether the Part D claim rejection was resolved. Resolution may be the result of the prescriber changing the prescription order to a formulary alternative, obtaining a prior authorization, or adjusting the prescription dose to meet formulary limitations. Providing the Medicare D beneficiary the Appeal Notice for each occurrence of the 569 reject code, regardless of the ultimate outcome, will cause beneficiary confusion as he/she may not understand that the reject is still under activities to resolve (and reach out to the plan prematurely), will result in overutilization of the notice, and will desensitize the true intention of the beneficiary's right to appeal.

Without a clearly defined process, beneficiaries will become confused as the proposed title of the Standardized Pharmacy Notice states "Your Prescription Cannot Be Filled." Initiating the appeal process for a claim rejection that has been resolved will result in increased beneficiary frustration

and administrative inefficiencies that will occur within the pharmacy, payer and customer support centers. Additionally, compliance monitoring will present unnecessary audit risks for the providers and Part D plans.

Recommendation:
CMS should clearly state the situations in which the Standardized Pharmacy Notice (CMS–10147) should be provided to the beneficiary. To mitigate beneficiary confusion and frustration, the situations should be limited to:

- *as a result of the Medicare D claim rejection, the Medicare D prescription claim is deleted from the pharmacy system and the beneficiary does not receive the intended medication therapy*
- *as a result of the Medicare D claim rejection, the beneficiary elects to pay cash or the prescription claim is covered by a coordinated benefit to which the NCPDP Approved Message Code of 018 is returned on the response*

The Accuracy of the Estimated Burden
CMS estimated the volume of Notices based on anecdotal information provided by PBMs. Using the 2010 benefit year where total claim volume was 1,123,860,661, it was estimated that approximately 10% of these transactions (112,386,066) incurred a reject. It was further estimated that 66% of these rejections are easily resolved; leaving 33% (37,087,402) that will require the notice. CMS estimated the annual cost burden of $8,341,326 strictly on hourly wages and did not consider the inventory costs associated in providing the notices.

CVS Caremark disagrees with the estimated reject rate, and is concerned with the lack of consideration to the additional costs of producing the notice. CVS Caremark reports overall claim rejection rate as 20% (224,772,132 transactions) for the 2010 benefit year. Based on CMS's estimate that 33% will require the Appeal Notice, the resulting annual volume would be 74,174,804. The cost for the paper and toner to print each notice is calculated to be $0.0088, with an annual cost of $653,480. This does not include hardware costs associated to replacing or adding printers to support the volume. In addition to increasing the annual cost burden to at least $9,000,000, the volume of rejects emphasizes the previously stated concerns. Distribution of the notice based only on the presence of NCPDP reject code 569 will desensitize the patient to the intent of the notice, increase beneficiary frustration and confusion, present unnecessary audit risks and compromise the goals of the Paper Reduction Act.

Recommendation:
The distribution of Standardized Pharmacy Notice (CMS–10147) should be limited to situations described in our above recommendation. Limiting the delivery of the information to situations where the beneficiary has not received the necessary drug therapy in a timely manner will ensure patient safety and avoid unnecessary confusion and frustration.

Ways to Enhance the Quality, Utility, and Clarity of the Information to be Collected

Appropriate design of pharmacy workflow is the key to successful delivery of services. A change in the workflow process is required as a result of the revisions to § 423.562(a)(3) and the associated regulatory provision at § 423.128(b)(7)(iii). While prescription claim rejection activity is available through various reporting or data warehouses, this information is typically not saved within the pharmacy practice system. Additionally, the patient or caregiver may not be in the pharmacy at the time the rejection occurs.

Detail could not be found within OCN: 0938–0975, CFR § 423.562(a)(3) or § 423.128(b)(7)(iii) which states the notice must be printed on a separate 8.5 x 11 sheet of paper. Information on whether the notice must be available in multiple languages also could not found.

The timing of the OCN: 0938–0975 federal register notice and the associated concerns as outlined above, present a significant risk in meeting the January 01, 2012 compliance date. Pharmacy providers will not have sufficient time or resources to program any changes that may be addressed in the final ruling. This timeline correlates to the fourth quarter of 2011, where resources will be dedicated to meeting the NCPDP vD.0 and X12 5010 HIPAA compliance date, Medicare D unique BIN/PCN and prescriber validation, which are all in addition to the busiest pharmacy benefit change period.

Recommendations:
To ensure the Appeal Notice is effectively communicated to the beneficiary, CVS Caremark requests that CMS allow optional enhancements to the CMS form 10147 by including the associated prescription number and a portion of the patient name. This additional information will allow the systems and/or the pharmacy team to correlate the specific claim rejection that could not be resolved, with the required Appeal Notice. While there are limitations to the information that can be provided on the notice due to the standard transactions, the beneficiary name and prescription number will provide a more personalized appearance to the beneficiary.

Allow the information within CMS form 10147 to be printed within the required font on the integrated prescription receipt. This allows pharmacy systems which translate workflow messages to the pharmacy team for specific scenarios including third party claim rejections, to also include the Appeal Notice language, improving communications and detail presented to the beneficiary. The associated prescription detail would be printed on one side of the receipt and the Appeal Notice information would be on a perforated sheet on the opposite side. We request this flexibility as an optional enhancement for pharmacy systems with the understanding that some pharmacies may need to support the model letter in its standard format due to system constraints.

If alternate languages are required, CVS Caremark requests that CMS form 10147 be provided with the applicable translations.

Appropriate implementation measures must be considered to facilitate effectiveness and consistency. Due to the timing of the OCN: 0938–0975 federal register notice, a twelve month

period should be allowed to comply with OCN: 0938–0975, CFR § 423.562(a)(3) and § 423.128(b)(7)(iii). At a minimum, a six month extension is needed in order to incorporate the applicable system changes as a result of the OCN: 0938–0975 final ruling.

August 1, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attn: Document Identifier/OMB Control Number
Room C-4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Director Shortt:

MAPRx brings together beneficiary, patient advocacy, family caregiver and health professional organizations committed to improving access to prescription medications and safeguarding the well-being of beneficiaries with chronic diseases and disabilities under the Medicare prescription drug benefit (Part D). On behalf of millions of Medicare beneficiaries with chronic conditions who rely on Part D for essential medications, the MAPRx Coalition appreciates this opportunity to submit comments in response to the revised standardized pharmacy notice: "Your Prescription Cannot Be Filled."

MAPRx commends Centers for Medicare and Medicaid Services (CMS) for proposing this beneficiary-friendly point-of-sale notice. It is something we have long advocated for those facing a prescription denial. MAPRx appreciates CMS making the effort to provide greater clarity and instructions for next steps for those beneficiaries who face such a denial.

In order to make the form even more useful and easier for beneficiaries to understand, MAPRx would like to make the following recommendations that will keep the form simple and direct while providing additional information. These changes are outlined below and organized in the same manner as the information on the form itself.

Heading: Your Prescription Cannot Be Filled
As currently constructed, the form immediately moves from the heading to an explanation of "Your Medicare Rights." MAPRx suggests adding a short explanatory

paragraph below the heading and prior to the section on Your Medicare Rights. This paragraph would briefly explain that the prescription cannot be filled because approval has been denied by the beneficiary's Part D plan when submitted by the pharmacy.

In addition, MAPRx recommends that the form include a brief checklist of possible reasons for denial. The pharmacist would then check the relevant reason so the beneficiary receiving the notice would know exactly why the plan has refused to cover the prescribed drug. This checklist would include as an option a checkbox entitled "Other" along with a space for the pharmacist to indicate the reason for the denial. This list should be simple, brief and in plain language, similar to this example:

> Your Medicare Part D prescription drug plan has denied coverage for the following reason:
>
> _____ Prior Approval Required by Plan
>
> _____ Exceeds Quantity Limits
>
> _____ Step Therapy Required
>
> _____ Other
> Reason provided by plan: _____

Including the above information at the beginning of the notice will clarify that the denial is strictly a matter of a coverage decision by the plan, rather than a pharmacy problem or other issue. It will also provide context for the information that follows.

Heading: Your Medicare Rights

This section informs the beneficiary of their right to request a coverage determination from the plan, including a request for an exception under certain circumstances.

MAPRx recommends simplifying some of the language in this section and breaking the information up into two parts. Many beneficiaries will not understand what a "coverage determination" is. This should be explained prior to conveying information on the request for an exception. We suggest that the opening sentence of this section use language such as, "You have the right to request a written explanation from your Medicare drug plan explaining the reason why the plan will not pay for your prescription. This is called a coverage determination."

Following this revised opening, the form should then explain that the beneficiary may request a special type of coverage determination called an exception. MAPRx also appreciates the fact that the form lists the circumstances under which a

beneficiary may be entitled to an exception. This will help ensure that those who may qualify for an exception will understand this and include the appropriate rationale in their request.

In the list of reasons for an exception request, MAPRx suggests changing the third bullet, which currently reads, "you need to take a non-preferred drug and you want the plan to cover the drug at the preferred drug price." We believe the following language would more explicitly convey to beneficiaries the rationale for an exception request: "you need to take a non-preferred drug but you believe your out of pocket expense for the drug is too expensive. You may appeal to ask that the drug be priced at the preferred drug cost to beneficiaries."

Heading: What You Need to Do

This section provides instructions on how to request a coverage determination from the beneficiary's Part D plan. It includes the specific information that the beneficiary will need to convey to the plan in order to receive the determination.

MAPRx suggests changing the order of the numbered items listed in this section, as well as slightly revising the language in item number one. For #1, MAPRx suggests changing the first sentence, which currently reads, "The prescription drug you believe you need." We propose that the revision use language such as, "The name of the prescribed drug that was not filled at the pharmacy." This is more precise wording than "that you believe you need."

For the list of four steps to obtain a coverage determination, MAPRx suggests changing the order. Item #3, the name of the pharmacy, would be placed second, after the name of the drug. Item #4, the date of rejection, would be moved to third place. Item #2, explaining the need for a doctor's statement to be submitted with an exception request, would be the final item on the list. The purpose of this re-order is to make the process more logical by telling the recipient beneficiary the things needed for all coverage determination requests first and ending with the additional information needed for an exception request. Since not all beneficiaries will request an exception, it makes sense to place this last on the list.

MAPRx would like to thank CMS for taking this important step to aid beneficiaries who face a prescription denial at the pharmacy. Since the beginning of the Part D program, MAPRx has urged CMS to require a point-of-sale notice for denials of prescriptions. It is important for a beneficiary who cannot obtain a prescribed medication to understand why and what to do in order to obtain the prescription. The proposed notice – with the suggested changes above – will provide the necessary information and steps to take to rectify the situation.

MAPRx appreciates the opportunity to comment on the revised standard pharmacy notice for prescription denials. Thank you for consideration of our input. For

questions related to MAPRx or the above comments, please contact Mary Beth Buchholz, Convener, MAPRx Coalition, at (202) 637-9732 ext 229 or Marybeth@maprxinfo.org.

Sincerely,

The ALS Association
American Autoimmune Related Diseases Association
Alzheimer's Association
Arthritis Foundation
Easter Seals
Epilepsy Foundation
Hemophilia Federation of America
Lupus Foundation of America
Medicare Rights Center
Men's Health Network
National Alliance on Mental Illness
National Council on Aging
National Kidney Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Osteoporosis Foundation
Parkinsons Action Network
RetireSafe
Spina Bifida Association
United Spinal Association

Medco Health Solutions, Inc.
Comments on the Pharmacy Notice
PRA CMS- 10147

Medco respectfully submits the following comments on the proposed Pharmacy Notice:

Title: "Your Prescription Cannot be Filled" is misleading to the beneficiary. The prescription can be filled; however, it will not be covered by the beneficiary's plan. We suggest: "**Your Prescription is not covered by your Medicare Drug Plan."**

For the Section titled: "**What you need to do**," we suggest changing the title to:
"What you need to do to request a coverage determination"

We also suggest the removal of #2 (*If you ask for an exception, your doctor or other prescriber will need to provide your drug plan with a statement explaining why you need the off-formulary or non-preferred drug or why a coverage rule should not apply to you*) in this section and making it a separate paragraph at the end of the numbered list.

We suggest the numbered list be as follows:

1. **Your name**
2. **Your member information from your plan membership card**
3. The prescription drug you believe you need. Include the dose and strength, if known.
4. The name **and address or phone number** of the pharmacy that could not fill your prescription.
5. The date your prescription was rejected at the pharmacy.

We suggest the following wording for the separate paragraph at the end:
When you request a coverage determination, your Medicare Drug Plan will contact your doctor or other prescriber to request information needed to make a coverage decision. Your drug plan will provide you with a written notice regarding their coverage decision. If coverage is not approved, the plan's notice will explain why coverage was denied and how to request an appeal if you disagree with the plan's coverage decision.

In order to fully explain the options available to thebeneficiary, we suggest adding the following language: "Your prescriber may also call your drug plan to initiate a coverage review."

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

August 1, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development
Attention: Document Identifier: CMS-10147
Control Number, Room C4–26–05,
7500 Security Boulevard
Baltimore, Maryland 21244–1850.

RE: Standardized Pharmacy Notice (Document Identifier CMS–10147)

Dear Sir/Madam:

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

The National Association of Chain Drug Stores (NACDS) thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to submit written comments in response to the information collection request for the standardized pharmacy notice. NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate 39,000 pharmacies, and employ more than 2.7 million employees, including 118,000 full-time pharmacists. They fill nearly 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States.

We support the goal of providing clear, easy to understand information to beneficiaries in the event their prescription medication is not covered by Medicare Part D. We offer our comments in the spirit of improving the implementation of the new requirement to provide beneficiaries a hard copy of the document, *Notice: Your Prescription Cannot Be Filled*. We are concerned that the current implementation plan will result in confusion for beneficiaries, and difficulties for pharmacies. NACDS offers the following concerns and asks CMS to consider the identified alternative solutions.

Title of the Notice

The title of the notice - Your Prescription Cannot be Filled – has the potential to cause confusion for beneficiaries and should be changed. The confusion for the beneficiary would arise from the fact that the prescription, while initially denied, may actually be filled by the time the patient arrives at the pharmacy to pick up their medication. For example, a pharmacist may have contacted the prescribing physician or health plan, and resolved the problem through a dosing change, a drug change, billing to a different plan or supplemental benefit, or a cash payment. According to the current guidance, pharmacies are required to give this notice to a patient every

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

time a denial code appears, even if a resolution is reached and the beneficiary obtains a prescription medication.

NACDS offers the following alternatives as a way to avoid these confusing situations and avoid the potential burden of increased time and expense in clarifying the issue. Situations requiring the notice should be limited to those that arise from the following:

- as a result of the Medicare D claim rejection, the Medicare D prescription claim is deleted from the pharmacy system and the beneficiary does not receive the intended medication therapy

- as a result of the Medicare D claim rejection, the beneficiary elects to pay cash or the prescription claim is covered by a coordinated benefit to which the NCPDP Approved Message Code of 018 is returned on the response

Other Areas of Concern

NACDS also has additional concerns with other areas, which if not resolved would unnecessarily increase the workload of the pharmacies.

Optional Information on Notice: The notice should allow for an option to include the drug name, prescription number and patient name on the notice so the patient has the correct information when contacting their plan. Having all of the information in one place would greatly reduce beneficiary confusion and would lead to a more productive encounter when calling their health plan.

Ability to Print Notice on Rx Label Stock: In addition to being able to provide the notice as a separate document, CMS should allow pharmacies the option to print the notice on the Rx label stock. Allowing this would greatly improve beneficiary convenience, and reduce costs and the environmental impact. Additionally, allowing this would give pharmacies the flexibility to work the provision of the notice more seamlessly into their workflow and processes, thus reducing the cost and time burden associated with providing the notice.

Optional Notification Forms: CMS should allow pharmacies the option to provide the notice via other forms of communication such as via telephone and email. Pharmacies have realized that beneficiaries do not want, nor do they need more paper. Pharmacies already receive a large number of complaints regarding the amount of paper provided with a prescription. Allowing alternative forms of communication would decrease the cost associated with printing numerous notices, which would likely be misplaced or thrown away.

Revise Language: The current language in the draft notice states "name of the pharmacy that could not fill your prescription." The language implies that the pharmacy did something wrong or was unable to perform as it should have when all the pharmacy did was act on behalf of the Part D plan. NACDS suggests revising this

language to read "The name of the pharmacy that filled or attempted to fill your prescription."

Clarification: NACDS would like to clarify whether or not the requirement to provide the written notice will apply to mail order providers.

Delay in Implementation: NACDS recommends delaying implementation of requirement by six months as the burden of meeting requirement by January 1, 2012 is too great on pharmacies. Because the notice has not yet been issued in its final version, necessary systems and processes changes at the pharmacy level have not been able to move forward. Pharmacies will need more than three or four months to implement these changes to ensure a smooth transition, especially during the new year which is traditionally a very busy time for pharmacy providers.

Thank you again for the opportunity to provide you with these comments. We look forward to partnering with you in the future on issues impacting retail pharmacy.

Sincerely,

Julie Helm Khani
Vice President, Public Policy

National Alliance of State Pharmacy Associations

2530 Professional Road, Suite. 202, Richmond, VA 23235
Phone: (804) 285-4431 Fax: (804) 612-6555 www.naspa.us

[**Submitted electronically via http://www.regulations.gov**]

August 1, 2011
CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development,
Attention: CMS-10147, CMS-10396 and CMS-R-246
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-10147; Information Collection: Standardized Pharmacy Notice

Dear Sir or Madam:

The National Alliance of State Pharmacy Associations (NASPA) promotes leadership, sharing, learning, and policy exchange among pharmacy leaders nationwide, and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health. NASPA was founded in 1927 as the National Council of State Pharmacy Association Executives (NCSPAE).

We welcome this opportunity to comment on the Agency Information Collections Activities regarding the Standardized Pharmacy Notice.

Standardized Pharmacy Notice
We appreciated and support the intent of increasing communication to Part D beneficiaries regarding how to contact their Part D plans to request a coverage determination, including a request for an exception to the Part D plan's formulary when a claim is rejected and cannot be filled by the pharmacy. However, the modification to eliminate the previously available option of posting the standardized notice at the pharmacy to require that a **printed copy** be provided to the patient if a prescription cannot be filled does cause concern.

We feel this mandate should be placed on Part D plans solely to communicate regarding their coverage determination directly to the beneficiary. They know "real time" if a claim rejects; they can send an automated email/phone call to the beneficiary of their rights. This should not preclude a pharmacy from voluntarily providing the information as well.

If this mandate to pharmacies advances,

- We would suggest restricting it to **print copy** notification is contrary to the move to an electronically connected health care system. It should be able to be distributed to the patient via their communication method of choice - emailed; faxed; telephonically; or as part of their PHR.
- We would request the effective date be 180 days after the final regulation is released so as to allow pharmacies adequate time to automate this process.
- We would request that all pharmacies, including mail service pharmacy, be required to distribute this notice. It makes no sense that this communication has to be given at POS but not via mail service.
- We would seek clarification that

- it only has to be distributed to the patient if no alternative to the originally presented prescription was agreed to by the plan and prescriber; we feel it would add confusion to the patient if notice is to be given when the pharmacists and prescriber has resolved the coverage determination issue by finding a suitable alternative product.
- a pharmacy would be allowed to add pertinent information that will assist the patient in communications with their health plan such as patient name, drug name requested, prescription id number on rejected claim, pharmacy name/identifier
- If the patient never returns to the pharmacy, because there is no prescription to "pick up", the requirement is negated. Often patients leave the prescription and call back to the pharmacy to see if it is "ready". In the case of a non-covered item, there is no reason for the patient to subsequently return to the pharmacy therefore fulfilling the requirement to "provide a Part D enrollee with a printed copy" is not possible.

Specific suggested revisions to notice:
Change title to:
"Notice: Your Insurance Didn't Pay for Your Prescription"
Rationale: The title currently is inaccurate. The pharmacy can fill any legal prescription; it is just that the insurance may not pay for it.

Under "Your Medicare rights":
We are concerned this section particularly is written on a too high of literacy level. Specifically, we are concerned that patients will not know what "coverage determination", "prior authorization", "quantity limits", "preferred and non preferred" mean.

Under "What you need to do":
- modify bullet three to read: "The name of the pharmacy that attempted to fill your prescription"
- In the last paragraph, change "will" to "must" in the sentence "Your Medicare drug plan **will** provide you with…."

As you finalize plans on the standardized pharmacy notice, NASPA respectfully urges you to consider these issues.

Thank you for the opportunity to comment.

Sincerely,

Rebecca P. Snead, RPh
Executive Vice President & CEO

July 29, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attn: Document Identifier/OMB Control Number
Room C-4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Director Shortt:

The National Council on Aging is a nonprofit service and advocacy organization. We are a national voice for older Americans and the community organizations that serve them. We bring together nonprofit organizations, businesses, and government to develop creative solutions that improve the lives of all older adults. The National Center for Benefits Outreach and Enrollment is housed at the National Council on Aging. The Center helps organizations enroll seniors and younger adults with disabilities with limited means into the benefits programs for which they are eligible so that they can remain healthy and improve the quality of their lives We thank you for the opportunity to comment on the draft Part D pharmacy point-of-sale notice of non-coverage notice.

We have consistently advocated for such a point of sale notice since the advent of Medicare Part D. Notice at the pint-of-sale is especially important because it is at the pharmacy counter that Part D plan enrollees first learn their prescriptions cannot be filled due to plan formulary issues. The notification they receive at that time is of critical importance to assure such beneficiaries take the steps necessary to request a coverage determination in order to secure the medications they have been prescribed. Because access to the coverage determination process is not intuitive and requires proactive steps on the part of the beneficiary *and* the prescriber, careful attention must be paid to the content and format of the point-of-sale notice. It is with the intent of partnering with CMS to offer people with Medicare the clearest messages possible as to how they should respond to the inability of a Part D plan pharmacy to fill a prescription that we submit our comments.

Introductory Paragraph Needed

In order to orient those receiving the notice to the issue at hand, prefatory language at the start of the draft point-of-sale notice is needed to explain the context – that the prescription cannot be filled for one of three reasons - the prescription is not on the plan formulary, or it is on the formulary, but subject to a limitation on access, such as prior approval, step therapy or a quantity limit, or that the drug is on a high tier that the plan member cannot afford. The explanation should begin with an explanation of a coverage determination; that Part D plan enrollees have the right to get from their plan an explanation as to why their coverage is being denied. This should be followed by plain language explanations of formularies, the three utilization management protocols, and tiering exception rights. Simple language explaining these alternative reasons why the pharmacy cannot fill

the prescription sets a context for the explanations of the affected individuals' rights and the actions they may take to seek redress. CMS has such language contained at www.Medicare.gov, as well as in the Medicare and You Handbook that could be replicated here.

Your Medicare Rights Section

The language used in the "Your Medicare rights" section describing the reasons why the pharmacist cannot fill the prescription is overly vague and does not clearly describe the reasons why the prescription cannot be filled. As an illustration of simpler language, on our www.MyMedicareMatters.org consumer Web site, here is how we describe the same three possibilities:

When can I ask for an exception?

- if you need to get a drug that is not on your Part D plan's drug list, OR
- if you need a drug that your plan has set limits on or has special rules about, OR
- if a drug you need costs more than you can afford.

If you have employed introductory section to explain these three options, simpler text in the "Your---Rights section will make more sense, especially to the many people with Medicare whose literacy level is low, or for whom English is not their primary language.

In this section, we urge you to include a check-off list that the pharmacist may use to indicate the specific reason for the Part D plan's coverage denial. Because the E-1 system returns the actual reason for the denial, it should not be overly burdensome to encourage pharmacies to simply check off the appropriate reason for the denial.

What you need to do section

This section is the most important, in that unless the recipient of this notice takes action, s/he will not have any chance of obtaining the denied prescription. Clarity is of the essence in this section. Accordingly, we suggest reordering the bullets and re-wording the text.

The section should begin with a bold-faced sentence informing the recipient that her prescription cannot be filled unless she takes immediate action. The first thing she needs to do is to call her plan and articulate that she is requesting an exception. The bullets should direct the beneficiary as to what to do when she calls her plan. Thus, the notice should forthrightly tell her that unless she calls the plan and asks for the exception, her prescription will not be filled. The notice should then clearly spell out the three items the recipient of the notice must provide to her plan in order to request that the prescription be filled through the exception process.

The three items should be bulleted; first is the name, and preferably the strength and dose of the denied drug. In this regard, the best option would be to have the pharmacy fill in the name of the drug. The next is the name of the pharmacy and the third is the date the prescription could not be filled.

Moreover, the information regarding the need for the prescriber to support the exception request should be separated from the items the individual needs to tell the plan, as this step involves a different action – the consumer contacting the prescriber and the prescriber contacting the plan. This, it should be made clear to the reader of the notice that in addition to calling the plan, the

enrollee must call her prescriber to obtain the required support for the exception. Further, it should be made clear that without that support the exception request must be denied. It should be emphasized that the prescriber must articulate facts to establish that the prescribed drug is the only one that will be efficacious for this patient and/or that all other drugs on the plan formulary have the potential for adverse side effects in this patient.

Finally, we recommend that the notice contain a reference to State Health Insurance Assistance Programs (SHIPs) that are available in every state to assist beneficiaries to pursue coverage determinations and exceptions. Customized reference to each state SHIP's toll-free Hotline would be the most effective means of telling affected Part D plan enrollees that they can get objective and informed help with their requests for coverage determinations and/or exceptions.

The National Council on Aging appreciates this opportunity to assist you in developing a revised point-of-sale notice of Part D prescription denials. If you have questions or would like to discuss this comment, please contact Hilary Dalin, Director, Benefits Access Policy and Programs, Hilary.dalin@ncoa.org.

Yours,

Howard Bedlin
VP, Public Policy and Advocacy

Nora Dowd Eisenhower
VP, Benefits Access

VIA Electronic Submission to http://www.regulations.gov

August 1, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10147/OCN: 0938–0975
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: CMS-10147; Information Collection: Standardized Pharmacy Notice

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on CMS's Information Collection regarding CMS's standardized pharmacy notice regarding Part D beneficiary rights when their Part D prescription cannot be filled. As CMS considers the burdens associated with moving from posted signs addressing such rights to a standardized notice to be given to beneficiaries, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives.

The National Community Pharmacists Association (NCPA®) represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a $93 billion health-care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions. NCPA members are the primary providers of drugs and pharmaceutical supplies to millions of Americans. Focusing on the Medicare Part D program, NCPA members are a primary access point for prescription medications for millions of Part D beneficiaries. A 2010 survey revealed that 30% of the average NCPA member pharmacy's business is Medicare Part D business.

Given the primary role that NCPA members play with regard to providing Part D drugs to Part D beneficiaries, we believe it is important to recognize the burden that Part D rules and regulations may impose upon community pharmacists. Burdensome administrative requirements can reduce the time that community pharmacists have available to devote to their patients. Accordingly, we urge CMS to appropriately recognize the burdens that administrative requirements, such as a standardized notice, may impose upon small business community pharmacies and how those burdens can be lessened.

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

Burdens and Costs Associated with a Paper Standardized Notice

NCPA members are overwhelmingly small businesses. As small businesses, they have greater burdens and costs under increased administrative requirements than larger businesses. The CMS plan to transition from a posted sign on Part D beneficiary appeal rights to a paper standardized notice is an example of such an administrative burden, which NCPA has concerns will have a greater impact on community pharmacy than CMS might have initially expected.

The posting of a sign with beneficiary appeal rights information is a one-time event, but it remains in place as a constant notice to beneficiaries. Accordingly, it requires little if any effort or cost on behalf of the pharmacy to maintain such a notice after the initial posting. However, the situation is the opposite with regard to CMS's plan to transition to a paper-based standard notice to be given out to each beneficiary with a rejected Part D claim. The latter requires an ongoing effort, as well as an ongoing expenditure of staff time. CMS has partially recognized such burdens and costs within its supporting statement for the paperwork burden requirement.

Despite CMS's recognition of the labor costs associated with transitioning to a paper-based standardized notice handout, CMS failed to assess, in its supporting statement, other costs associated with the transition, including the cost of a manual versus automated process to distribute the standardized notice and the paper, ink and copying costs expended to generate a paper notice for each beneficiary with a rejected Part D claim. Regarding rejected claims, NCPA seeks clarification from CMS that the notice only be distributed when no alternative therapy is agreed to by the pharmacist and prescriber. In other words, the notice should not be required to be distributed when the pharmacist resolves the issue by working with the prescriber to find a suitable alternative product.

NCPA is concerned that electronic systems may not be in place by 2012 that will automatically generate a printout of a point of sale standardized notice each time a beneficiary's Part D prescription cannot be filled. If such systems will not be in place by 2012, then even more staff time will be required to manually print out the standardized notice each time a beneficiary's Part D prescription cannot be filled. CMS does not appear to have taken into consideration the impact on pharmacies in terms of pharmacy staff time required to meet this mandate should there not be an electronic process in place to automatically generate standardized notices. NCPA is also concerned with an apparent lack of consistency on the part of CMS with regard to how pharmacies obtain this form for subsequent distribution to beneficiaries. CMS states that each Medicare Part D plan sponsor must arrange with its network pharmacies for the distribution of this notice to Part D enrollees. NCPA asks that CMS institute a process where all community pharmacies can go to one location on the CMS website to print the final version of the standardized notice.

As to the issue of paper, ink and copying costs, NCPA conducted a survey of our members to assess the relevant burden likely to be imposed by this transition. NCPA's survey results demonstrate that almost 35.5% of our members have 0 to 10 situations per week, where a beneficiary's Part D claim is rejected at the point of sale. Likewise, another 35.5% of our members face this situation 10 to 20 times per week. This means that under the proposed transition, many of our members will have to provide copies of the standardized notice to Part D beneficiaries 500 to 1,000 times per year. According to our members, 33.3% estimate the paper, copying, printing and ink costs for these efforts to be anywhere from 0 to $100 per year. Another 37.5% estimate those costs to be $100 to $500 per year. The remainder of our surveyed members estimate the costs to be over $500 per year.

Our members operate on thin profit margins and are small businesses, as discussed above. Accordingly, hundreds of extra dollars expended per year can have a significant impact on our members. Moreover, these new standardized notice-related costs are in addition to many other costs, which our members already have to expend to participate in Medicare and Medicaid, including, but not limited to enrollment application fees, surety bond fees, accreditation fees and document retention services associated with the 10 year Part D requirements, which go above and beyond state board of pharmacy document retention requirements. Though each of these separate fees and costs may not be substantial, combined they become unduly burdensome on small business community pharmacies, and if they are substantial enough, may lead to pharmacies ceasing to provide certain Medicare and Medicaid products and services.

More generally, NCPA remains concerned that CMS did not conduct an appropriate small business impact analysis within the April 15, 2011 Final Rule regarding Medicare Part D, as required by the Regulatory Flexibility Act. Within the Final Rule, CMS's regulatory impact analysis focuses entirely upon the burden to be imposed on processors and Part D plans. To the extent that the regulatory impact analysis mentions the impact on pharmacies at all, it fails to carve out small business pharmacies, like NCPA's members. In other words, CMS has failed to conduct an adequate small business impact analysis of this proposed change on small business pharmacies.

Also, NCPA asks that all pharmacies, including mail order pharmacies, be required to distribute the standardized notice. NCPA has concerns that CMS is only requiring this notice be generated at point-of-sale and not by mail order companies.

Conclusion

Because of the total costs and burdens associated with the transition to a paper-based standardized notice, NCPA urges CMS to reevaluate the small business burdens imposed by the transition. NCPA also requests that CMS reconsider the decision to make the transition or, at a minimum, to consider options for reducing the costs and burdens to community pharmacies associated with this transition. Moreover, NCPA maintains that CMS should mandate that Part D plans bear the costs associated with this transition to a paper-based standardized notice, not the pharmacies. Part D plans are in a better position to bear the burden of these costs and the standardized notice itself has more to do with the Part D plans and appeals of plan decisions than it does with the pharmacies and the services that they provide.

NCPA appreciates the opportunity to comment on the standardized pharmacy notice for Part D beneficiaries with point of sale rejected claims. Please do not hesitate to contact Chris Smith by email at chris.smith@ncpanet.org, or by telephone at (703) 600-1185, if you have any questions.

Sincerely,

John M. Coster

John M. Coster, Ph.D., R.Ph.
Senior Vice President, Government Affairs
and Director, NCPA Advocacy Center

Tennessee Pharmacists Association

500 Church Street, Suite 650 Nashville, Tennessee 37219
Phone: 615/256.3023 Fax: 615/255.3528
tpa@tnpharm.org www.tnpharm.org

[**Submitted electronically via http://www.regulations.gov**]

August 1, 2011

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development,
Attention: CMS-10147, CMS-10396 and CMS-R-246
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-10147; Information Collection: Standardized Pharmacy Notice

Dear Sir or Madam:

The Tennessee Pharmacists Association (TPA), on behalf of pharmacists in all practice settings in Tennessee and the patients they serve, appreciates the opportunity to submit our comments regarding the Center for Medicare and Medicaid Services (CMS) Agency Information Collections Activities regarding the Standardized Pharmacy Notices. Standardized Pharmacy Notice.

Standardized Pharmacy Notice

TPA appreciates and supports the intent of increasing communication to Part D beneficiaries regarding how to contact their Part D plans to request a coverage determination, including a request for an exception to the Part D plan's formulary when a claim is rejected and cannot be filled by the pharmacy. However, the modification to eliminate the previously available option of posting the standardized notice at the pharmacy to require that a **printed copy** be provided to the patient if a prescription cannot be filled does cause concern.

TPA feels this mandate should be placed on Part D plans solely to communicate regarding their coverage determination directly to the beneficiary. They know "real time" if a claim rejects; they can send an automated email/phone call to the beneficiary of their rights. This should not preclude a pharmacy from voluntarily providing the information as well.

If this mandate to pharmacies advances,

- We would suggest restricting it to **print copy** notification is contrary to the move to an electronically connected health care system. It should be able to be distributed to the patient via their communication method of choice - emailed; faxed; telephonically; or as part of their PHR.
- We would request the effective date be 180 days after the final regulation is released so as to allow pharmacies adequate time to automate this process.

- We would request that all pharmacies, including mail service pharmacy, be required to distribute this notice. It makes no sense that this communication has to be given at POS but not via mail service.
- We would seek clarification that
    - it only has to be distributed to the patient if no alternative to the originally presented prescription was agreed to by the plan and prescriber; we feel it would add confusion to the patient if notice is to be given when the pharmacists and prescriber has resolved the coverage determination issue by finding a suitable alternative product.
    - a pharmacy would be allowed to add pertinent information that will assist the patient in communications with their health plan such as patient name, drug name requested, prescription id number on rejected claim, pharmacy name/identifier
    - If the patient never returns to the pharmacy, because there is no prescription to "pick up", the requirement is negated. Often patients leave the prescription and call back to the pharmacy to see if it is "ready". In the case of a non-covered item, there is no reason for the patient to subsequently return to the pharmacy and, therefore, fulfilling the requirement to "provide a Part D enrollee with a printed copy" would not possible.

Specific suggested revisions to notice:
Change title to:
"Notice: Your Insurance Didn't Pay for Your Prescription"
Rationale: The title currently is inaccurate. The pharmacy can fill any legal prescription; it is just that the insurance may not pay for it.

Under "Your Medicare rights":
We are concerned this section particularly is written on a too high of literacy level. Specifically, we are concerned that patients will not know what "coverage determination", "prior authorization", "quantity limits", "preferred and non preferred" mean.

Under "What you need to do":

- modify bullet three to read: "The name of the pharmacy that attempted to fill your prescription"
- In the last paragraph, change "will" to "must" in the sentence "Your Medicare drug plan **will** provide you with…."

As you finalize plans on the standardized pharmacy notice, TPA respectfully urges you to consider these issues.

Thank you for the opportunity to comment.

Sincerely,

Baeteena M. Black

Baeteena M. Black, D.Ph.
Executive Director