

Comments Received on Standardized Pharmacy Notice (CMS–10147)
August 2011

Organization	Document (notice, instructions)	Page # (if applicable)	Issue/Comment	CMS Response
Argus	Notice		<p>Distribution of Notice</p> <p>Commenter seeking clarification on when notice is to be given to enrollee. Is notice given in cases where Rx is not filled/covered by Part D, but is filled by a secondary payer?</p>	<p>If Medicare Part D rejects the claim at POS (Part D does not pay any portion/Rx not filled by Part D), the pharmacy must provide the enrollee with the notice, even if the Rx is paid/filled by a secondary insurer. Any Part D rejection at POS that cannot be resolved triggers distribution of the pharmacy notice.</p>
NACDS	Notice		<p>Commenter believes CMS should allow pharmacies to print the pharmacy notice on prescription label stock.</p>	<p>To afford some flexibility, “on demand” printing on Rx label stock paper will be permitted, so long as a 12-pt. font is used. Pharmacy notice instructions will specify that 12 pt. font must be used when printing notice.</p>
<p>NACDS</p> <p>NASPA</p> <p>TPA</p> <p>NASPA</p> <p>TPA</p>	Notice		<p>CMS should allow pharmacies to communicate the info other ways, such as by telephone or e-mail; seeking clarification on distribution if the enrollee never returns to the pharmacy to pick up the medication because there is no prescription to “pick up.”</p>	<p>Electronic distribution of the notice will be permitted (so long as enrollee or appointed rep has provided an e-mail address and indicated acceptance of that method of communication); this will afford some flexibility when alternative pharmacy settings (e.g., mail order, LTC) are involved in the transaction.</p> <p>The content of the pharmacy notice cannot be delivered via telephone exclusively. The information in the</p>

				notice must be given to the enrollee in writing.
American Pharmacists Association (APhA) CVS Caremark NACDS NCPA NASPA TPA	Notice		Distribution of Notice Seeking clarification re: distribution of notice. Does the notice have to be provided in every instance when the reject code is returned to the pharmacy? Commenter advocating that the notice should only be required when there is no point of sale (POS) resolution. Distribution should be limited to: - Medicare Part D rejection; bene does not receive Rx (no POS resolution) - As a result of Part D rejection, bene pays cash or Rx is covered by coordinated benefit to which code 018 is returned on response	As previously noted (above), the pharmacy notice is provided anytime Part D rejects the claim and the rejection is not resolved at POS. The notice must be provided if Part D rejects the claim, but a secondary/supplemental payer fills the script.
BCBSA	Notice		Distribution of Notice Commenter seeks clarification on entity responsible for distributing notice	The instructions clearly state that the pharmacy is responsible for providing the notice. In addition, the regulations clearly state that plan sponsors must arrange with network pharmacies for distribution of the notices.
Argus	Notice		Delete reference to prescription being "rejected" at the pharmacy since there would be no rejected claim if a secondary payer covered the fill.	Disagree; we believe a reference to the claim being rejected is accurate. Nonetheless, in the interest of clarity, we have modified the language to state: "The date you attempted to fill your prescription."

Argus	Notice & Instructions		Commenter believes LTC pharmacies should be exempt from providing the notice.	Disagree. All pharmacies are obligated to provide the notice (including LTC and mail order).
APhA	Notice		Expressed concern regarding potential for burden and cost shift to pharmacy to implement this requirement. Encourages CMS to explore ways to require plans to provide information to beneficiaries.	Comments are outside the scope of this PRA package. The regulatory requirement that Part D plan sponsors arrange with network pharmacies for distribution of this notice was finalized per rulemaking (CMS-4144-F).
APhA CVS Caremark NACDS NASPA TPA	Notice		Customization Clarify whether customized, electronic notice is permitted; should not be restricted to paper notices Allow optional enhancements of Rx number and portion of the patient's name. Allow notice to be printed on the integrated prescription receipt.	We have added optional fields to the notice for the enrollee's name and the drug/Rx #. This is the only type of "customization" permitted. As stated above, an electronic/e-mail notice is permitted. In addition, the notice can be printed on pharmacy stock paper ("integrated prescription receipt") so long as a 12 pt. font is used.
APhA	Notice		Clarify whether reject code indicates that individual is a Part D enrollee (not on private plan); ensure continued improvements in claims messaging/NCPDP standards; ensure Part D enrollees receive information on coverage determinations from the plan sponsors.	Comments outside the scope of this PRA package. NCPDP is responsible for setting coding/messaging standards for the industry that are HIPAA compliant. On the second point, Part D plan sponsors are obligated to provide

				enrollees w/ information on coverage determinations and appeals.
APhA NACDS NCPA NASPA TPA	Instructions		Clarify whether distribution of this notice applies to mail order pharmacies.	See response above.
APhA	Notice		Translations Clarify requirements related to distribution of notice in other languages	CMS will continue to provide a notice translated in Spanish.
Center for Medicare Advocacy (CMA)	Notice		Translations Strongly recommends that CMS provide plans with model translations for 10-15 languages. Alternatively, pharmacies should be told to include information on contacting the plan to interpreter assistance.	CMS will continue to provide a pharmacy notice translated in Spanish. We expect the Spanish version to be distributed, when appropriate. In addition, plan materials address translation services and the notice refers enrollees to the plan membership card, toll-free line, and website.
APhA NASPA TPA	Notice		Title of Notice Consider revising title to something like “Your Insurance Did Not Pay for your Prescription” so as not to suggest the pharmacy made an adverse coverage decision.	Based on comments received, we have decided to retain the current title “Medicare Prescription Drug Coverage and Rights”. Commenters expressed concern that any reference to “your prescription cannot be filled” is likely to mislead beneficiaries into believing that the pharmacist has made a coverage

				determination on behalf of the plan.
Medco	Notice		<p>Title of Notice</p> <p>Title is misleading-prescription can be filled but will not be covered by the beneficiary's plan. Suggested title "Your Prescription is not covered by your Medicare Drug Plan"</p>	Disagree. A POS transaction is not a coverage determination unless a plan chooses to treat it as such. As noted above, we are retaining the current title "Medicare Prescription Drug Coverage and Your Rights".
NACDS	Notice		<p>Title of Notice</p> <p>Title is confusing and should be changed; initially denied prescription may be filled by the time the patient arrives at the pharmacy to pick up if the pharmacy has contacted the prescriber and resolved the problem through a dosing change, drug change, billing to a different plan or supplemental benefit, or a cash payment.</p>	As noted above, we are retaining the title "Medicare Prescription Drug Coverage and Your Rights" and will clarify that if the reason for the reject is resolved at the point of sale, distribution of the notice is not required.
BCBSA	Notice		<p>Title of Notice</p> <p>Proposed title may mislead beneficiaries; will conclude plan does not cover the drug. Commenter suggests retaining current title ("Medicare Prescription Drug Coverage and Your Rights").</p>	Agree. We are retaining the current title "Medicare Prescription Drug Coverage and Your Rights".

Medco	Notice		Change title of section “What you need to do” to “What you need to do to request a coverage determination”	Disagree. We believe the language is clear and doesn’t require this change.
Medicare Access for Patients Rx (MAPRx)	Notice		Commenter suggests adding short explanatory paragraph below title explaining that Rx can’t be filled because approval has been denied by the Part D plan.	Disagree. The POS transaction is not a denied coverage determination, as suggested by the commenter.
Medco	Notice		Suggest adding to numbered list: enrollee name, member information, address and phone number of the pharmacy	Disagree. The enrollee only needs to provide enough information for the plan to identify the rejected claim and we don’t believe the notice requires this change. We have added optional fields at the top of the notice for the enrollee’s name and the drug/Rx #.
CMA	Notice		Individually tailored notices at the point of sale are legally required.	Comment is outside the scope of this PRA package. CMS has again recently explained in rulemaking (CMS-4144) that individually tailored POS notices are neither required by law nor feasible based on current POS technology.
CMA MAPRx NCOA	Notice		Include a brief checklist of possible reasons for denial. - Prior Approval Required by Plan - Exceeds Quantity Limits - Step Therapy Required - Other (free text field)	This type of customization is not supported by current coding. The pharmacist is unlikely to have the information necessary to complete these types of check boxes.
MAPRx	Notice		Revise intro sentence to: “You have the	The commenter’s suggested revision

			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.”	incorrectly suggests that the POS rejection is a coverage determination. The intro sentence (as written) correctly indicates the right to request a coverage determination. In addition, the last paragraph of the notice correctly explains that if the plan issues an unfavorable coverage determination, the enrollee will receive a written explanation.
MAPRx	Notice		Commenter suggests that the 3 rd bullet point (list related to requesting an exception) be changed to: “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.”	Disagree. Again, comment suggests that the next step is an appeal, but the POS transaction is not a coverage determination. In addition, the proposed language inappropriately suggests that the standard for a tiering exception is the belief that cost-sharing for the drug is too expensive.
NASPA TPA	Notice		Language in the “Your Medicare Rights” section is written on too high a literacy level; enrollees will not understand: coverage determination, prior authorization, quantity limits, preferred v. non-preferred.	Disagree. We believe enrollees will be able to understand this notice and if they do have questions, those can be answered by the pharmacy providing the notice, the plan, a family member, other Part D publications they have received, a SHIP counselor, or 1-800-Medicare.
CMA	Notice		A reference to “Medicare health plan” should be added to reflect that some individuals get drug coverage from an MA-PD.	Disagree. Other CMS publications, including <i>Medicare & You</i> , use the term “Medicare drug plan” to cover both PDPs and MA-PDs.

CMA	Notice		Add “or if you have already met the coverage rule” to 3 rd bullet point	Disagree, but we have modified the intro paragraph to more clearly account for coverage determination requests that do not involve exceptions, which should alleviate commenter’s concern.
NACDS NAPSA TPA	Notice		Change “name of the pharmacy that could not fill your prescription” to “name of the pharmacy that filled or attempted to fill your prescription”	Disagree. We do not believe the commenter’s change is necessary because it doesn’t change the meaning of the language we have proposed.
NCOA	Notice		Notice should explain 3 reasons that prescription cannot be filled: not on the formulary, on formulary but subject to UM limitation, or on a higher tier than the member can afford.	Disagree. This language would be duplicative of other publications enrollees receive, the notice already correctly states that Part D rejected coverage of the drug (for any reason), and the 3 rd reason would not result in the notice being given (because in that case the drug would be covered).
NCOA	Notice		Language in “Your Medicare rights” section is overly vague and does not describe the reasons the prescription cannot be filled.	Disagree. Although we have revised the proposed language to clarify when an enrollee can request a coverage determination, we do not believe it is advisable to detail every reason a prescription cannot be filled, and pharmacy messaging does not allow for a notice tailored specifically to each POS rejection.
NCOA	Notice		Notice should include plain language of formularies, UM protocols and tiering exception rights; replicate language that is on medicare.gov with respect to this	Disagree. As commenter indicates, this language is available in other publications and we believe it would be

			situation	duplicative in this notice. In addition, we believe there is value in retaining the one-page length of this notice.
CMA	Notice & Instructions		Require distribution of notice if beneficiary says s/he cannot afford a prescribed non-preferred drug	Disagree. Generally, the notice is given if the Rx can't be filled/paid for by enrollee's Medicare drug plan. An enrollee claiming financial hardship does not trigger delivery of the pharmacy notice. Information specific to requesting tiering exceptions is also provided by plan materials (e.g., EOC) and various CMS pubs.
CMA MAPRx Medco NCOA	Notice		Reorder the 4 steps. Move item #2 to end of list b/c not all enrollees will request an exception/reordering will make the process more logical by telling bene info need for all coverage determination requests first and ending w/ the additional info for an exception.	Agree. Notice revised per suggestion.
NCOA	Notice		Notice should include instructions for enrollee to contact their prescriber to obtain a supporting statement and articulate what the supporting statement should include.	Disagree. Plans are required to solicit a supporting statement and clinical information so the enrollee does not have to do this. Additionally, we have clarified that prescribers may contact the plan to initiate the coverage determination. Other publications include information on supporting statements for exceptions and we do not believe this notice should duplicate that information. As previously stated, we believe there is value in retaining the

				one-page length of this notice.
MAPRx	Notice		Revise #1 as follows: The name of the prescribed drug that was not filled at the pharmacy.” More precise wording.	Agree. Change made.
NCOA	Notice		Notice should include a reference to SHIPs, with a customized reference to each SHIP’s hotline number.	Disagree. Pharmacies will not have the capability to customize these notices for each state, and this information is duplicative of other publications already provided to enrollees. In addition to referring to plan materials, we’ve added a reference to 1-800-Medicare.
CMA	Notice		Add a #5 to the list that reflects enrollee’s right to request an expedited coverage determination/include adjudication timeframes.	Agree. We have not added a #5 to the list, but we have added a sentence to the notice explaining the right to request an expedited coverage determination.
Medco	Notice		Add sentence for 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.”	Disagree. The notice does not require this language and this information is clear in other Medicare publications. The notice includes language regarding supporting statements for exception requests.
NASPA	Notice		Change “will” to “must” in last sentence, “Your Medicare drug plan will provide you with...”	Disagree. This change is not necessary. The use of “will” more clearly puts the enrollee on notice as to what documentation he/she can expect to receive from the plan after requesting a coverage determination.
TPA				
Medco	Notice		Add the following language: “Your prescriber may also call your drug plan to	Agree. We have revised language to clarify that both enrollees and

			initiate a coverage review.”	prescribers may request coverage determinations.
CVS Caremark NCPA	Notice		Burden Estimate CMS based burden on wages, but did not consider inventory costs; commenter disagrees with estimated reject rate and is concerned with lack of consideration of additional costs (e.g., paper, toner, hardware).	The commenter’s higher estimates are based on an assumption that the notice must be given whenever the reject code is returned to the pharmacy. The notice does not need to be provided if there is resolution to the rejection at POS, which addresses the commenter’s concerns regarding the frequency with which the notice will need to be distributed. Therefore, we believe our estimates are appropriate.
CVS Caremark NACDS NASPA NCPA NASPA TPA	Notice		Timing/Implementation concerns Commenters concerned that pharmacy providers will not have sufficient time to program changes prior to 1/1/2012 Commenters believe 6-12 month delay is appropriate; at a minimum, 6 months is needed to incorporate applicable systems changes.	Regulation requires distribution of this notice as of 1/1/2012. We are aware that industry needs sufficient time to program systems to accommodate this change and we will make a decision regarding implementation based on the date of OMB approval.
NCPA	Notice		Commenter requests that CMS post the final version of the notice on the CMS website.	Agree. The notice will be posted on the CMS website once finalized.
NCPA	Notice		Commenter states that costs for the new	This comment is outside the scope of

			standardized notice are in addition to many other costs necessary to participate in Medicare and Medicaid, including enrollment application fees, surety bond fees, document retention services, etc.	this PRA package.
NCPA	N/A		CMS did not conduct an appropriate small business impact analysis in the April 15, 2011 final rule regarding distribution of this notice (focused on processors and part D plans and did not carve out small business pharmacies)	This comment is outside the scope of this PRA package.
NCPA	Notice		CMS should reconsider the decision to require the paper-based standardized notice, and should mandate that Part D plans bear the costs associated with the notice, not the pharmacies.	This comment is outside the scope of this PRA package.
NASPA TPA	Notice		Mandate should be placed on Part D plans to communicate directly to the beneficiary; plans know "real time" if a claim rejects and can send an automated email/phone call to the beneficiary of their rights.	This comment is outside the scope of this PRA package.