

**Supporting Statement – Part A**  
**Uniform Exceptions and Appeals §423.562(a)(3) and Voluntary de Minimis §423.70(f)**

**A. Background**

**Uniform Exceptions and Appeals §423.562(a)(3)**

Section 3312 of PPACA amends section 1860D-4(b)(3) of the Act by adding a new section (H) that will require each PDP sponsor of a prescription drug plan to use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and to provide instant access to such processes by enrollees through a toll-free telephone number and an Internet website.

Since the inception of the Part D program, we have received numerous comments, especially from beneficiary advocacy groups, suggesting the coverage determination and appeals processes are too complex and difficult for enrollees to navigate. The commenters recommended streamlining the existing coverage determination and appeals processes in order to simplify the plan appeals procedures for both enrollees and providers. The most significant concerns noted by commenters involve access to the Part D coverage determination and redetermination processes. For a variety of reasons, enrollees often have difficulty making initial requests for coverage. Over time, plan sponsors developed plan-specific forms for requesting coverage, and often have multiple request forms that are drug-specific. As a result, enrollees often have difficulty locating or obtaining these plan-specific request forms, and determining which form should be used for their particular request. Even when enrollees are able to locate and complete the appropriate request forms, they may have trouble determining where the forms should be submitted, because plan sponsors often have multiple addresses, telephone numbers, and fax numbers, and it is not clear which address or phone number should be used to submit a particular request. Commenters indicate these elements create a process that is quite overwhelming and frustrating for enrollees, and for those who try to assist them.

In accordance with the new section 1860D-4(b)(3)(H), we are revising the regulation at §423.128 paragraphs (b)(7) and (d) to specifically provide three mechanisms that plan sponsors must have in place in order to meet the uniform appeals requirements of 1860D-4(b)(3)(H) of the Act.

**Voluntary de Minimis §423.70(f)**

The proposed voluntary de minimis provisions would permit Part D plans to volunteer to waive a de minimis amount of the Part D premium above the low income benchmark and, thus, avoid losing LIS beneficiaries to reassignment. We perform reassignments to ensure that beneficiaries whom we originally assigned to a zero premium plan will not incur a new premium liability when their current plan's premium goes above the LIS benchmark in the following year.

**B. Justification**

## 1 . Need and Legal Basis

### **Uniform Exceptions and Appeals §423.562(a)(3)**

In accordance with section 1860D-4(b)(3)(H) of the Act, we propose to revise §423.128 at paragraphs (b)(7) and (d) to specifically provide three mechanisms that plan sponsors must have in place in order to meet the uniform appeals requirements of 1860D-4(b)(3)(H) of the Act.

Specifically, at §423.128(b)(7), we propose to add paragraph (i) to require that plan sponsors make available standard forms to request coverage determinations and redeterminations. CMS also propose to add paragraph (ii) to §423.128(b)(7), which would require sponsors to develop a web-based electronic interface that allows an enrollee (or an enrollee's prescriber or representative) to immediately request a coverage determination or redetermination via a plan's secure website. The interface would be the "electronic equivalent" of the paper coverage determination and appeals forms proposed at §423.128(b)(7)(i). Similarly, we propose to revise §423.128(d) by requiring sponsors to provide a toll-free telephone line for requesting coverage determinations and redeterminations. The burden associated with these proposed requirements involves collecting the coverage determination request information submitted through the various proposed processes.

We also propose to require Part D sponsors to modify their electronic transactions to pharmacies so that they can transmit codes instructing pharmacies to distribute notices at the point-of-sale (POS). That is, pharmacies and processors will be required to program their systems to relay the message at the pharmacy to distribute the appeal notice. In cases when a prescription cannot be filled as written, Part D sponsors are required under §423.562(a)(3) to arrange with their network pharmacies to distribute a pharmacy notice advising the enrollee of his or her right to contact the plan to request a coverage determination. We estimate that the burden on processors will be the programming to send the code or billing response to the pharmacy, as well as revisions to the contract requirement with the pharmacy.

### **Voluntary de Minimis §423.70(f)**

Section 3303(a) of the ACA modifies section 1860D-14(a) of the Act by creating a new subsection (5) that permits PDPs and MA-PD plans to waive a de minimis monthly beneficiary premium for low income subsidy (LIS) eligible individuals who are enrolled in the plan. The provision goes on to prohibit the Secretary from reassigning LIS individuals if they are enrolled in a plan that has volunteered to waive the de minimis amount.

Section 3303(b) of ACA modifies section 1860D-1(b)(1) of the Act that permits the Secretary to include PDPs and MA-PD plans that waive the de minimis amount in the auto-enrollment process that we use to enroll those LIS eligible individuals who fail to enroll in a Part D plan. If these plans are included in the process, and there is more than one plan, the statute directs enrollees be randomly assigned.

CFR §423.34 and §423.780 have been amended to codify the new statutory requirements. To

conform with the statutory deadline, the proposed provisions will be effective January 1, 2011.

## 2. Information Users

### **Uniform Exceptions and Appeals §423.562(a)(3)**

The information collected is associated with the prescription drug plan's coverage determination and redetermination process requirements under Medicare Part D. Part D sponsors will collect coverage determination requests submitted via mail, phone, and electronically. Part D sponsors will also be required to distribute claim specific beneficiary notification at the pharmacy which will require the sponsor program their systems to ensure pharmacies distribute appeal notices at the point-of-sale.

### **Voluntary de Minimis §423.70(f)**

CMS will use the responses to prevent beneficiaries from being reassigned from the plans that volunteered to waive the de minimis.

## 3. Use of Information Technology

### **Uniform Exceptions and Appeals §423.562(a)(3)**

The coverage determination process begins when the beneficiary submits a coverage determination (appeal) directly to the Part D plan sponsor. The submission of the coverage determination occurs via mail, electronically, or phone. Approximately 4.2 percent of total coverage determination requests are submitted via secure websites.

This collection is not currently available for completion electronically.

This collection does not require a signature from the respondent(s).

Whether or not this collection can be made available electronically is not applicable.

This is a new requirement from ACA that is effective January 1, 2012.

### **Voluntary de Minimis §423.70(f)**

One hundred percent of the data is submitted electronically.

## 4. Duplication of Efforts

### **Uniform Exceptions and Appeals §423.562(a)(3)**

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

### **Voluntary de Minimus**

This collection does not duplicate efforts.

5. Small Businesses

**Uniform Exceptions and Appeals §423.562(a)(3)**

Collection does not impact small businesses.

**Voluntary de Minimis §423.70(f)**

Not Applicable

6. Less Frequent Collection

**Uniform Exceptions and Appeals §423.562(a)(3)**

The consequence to Federal program or policy activities if the collection is not conducted is twofold: 1) Medicare beneficiaries will not have the ability to submit coverage determinations to Part D sponsors in order to obtain their prescription drugs; and, 2) Failure to obtain drugs may result in the beneficiary utilizing more costly care at the expense of the Federal government (e.g., hospitalization paid for by Medicare Part A).

**Voluntary de Minimis §423.70(f)**

Plans are required to volunteer annually.

7. Special Circumstances

**Uniform Exceptions and Appeals §423.562(a)(3)**

There may circumstances when the beneficiary needs to submit additional information to the Part D sponsor in order to support their request for coverage determinations. For example – a clinical explanation from his/her physician explaining why the drug the beneficiary is taking needs to be covered by the plan.

**Voluntary de Minimis §423.70(f)**

Not Applicable

8. Federal Register/Outside Consultation

PRA STAFF

## 9. Payments/Gifts to Respondents

Uniform Exceptions and Appeals §423.562(a)(3)

Not applicable.

Voluntary de Minimis §423.70(f)

Not Applicable

## 10. Confidentiality

Uniform Exceptions and Appeals §423.562(a)(3)

Confidentiality is assured to respondents as the information exchanged during the coverage determination process is subject to Federal health privacy standards.

Voluntary de Minimis §423.70(f)

Not Applicable

## 11. Sensitive Questions

Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that we commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific use of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

Voluntary de Minimis §423.70(f)

Not Applicable

## 12. Burden Estimates (Hours & Wages)

We estimate that all 731 plan sponsors will receive a total of 484,468 coverage determination requests submitted by mail on the standardized coverage determination request form, and that it will take 10 minutes to enter the information submitted in each request form into a claims processing system, for a total annual burden of 80,745 hours. We also estimate that all plan sponsors will receive a total of 52,086 coverage determination requests submitted through secure websites, but that this process will not create an additional burden for plan sponsors beyond that required for requests submitted by mail because enrollees will enter information into a claims processing system themselves. Finally, we estimate that all plan sponsors will receive a total of 690,064 coverage determination requests submitted by telephone, and it will take 10 minutes to

enter the information submitted by phone into the claims processing system, for a total annual burden of 115,011 hours. The burden associated with the redetermination process is exempt under 5 CFR 1320.4(a)(2) because a redetermination is an administrative action and information collected when conducting an administrative action is not subject to the PRA.

We also proposed to require Part D sponsors to modify their electronic transactions to pharmacies so that they can transmit codes instructing pharmacies to distribute notices at the point-of-sale (POS). That is, pharmacies and processors will be required to program their systems to relay the message at the pharmacy to distribute the appeal notice. In cases when a prescription cannot be filled as written, Part D sponsors are required under §423.562(a)(3) to arrange with their network pharmacies to distribute a pharmacy notice advising the enrollee of his or her right to contact the plan to request a coverage determination. We estimate that the burden on processors will be the programming to send the code or billing response to the pharmacy, as well as revisions to the contract requirement with the pharmacy. We estimate that the number of hours for each processor (28 PBMs and 12 plan organizations) to perform these tasks will be 40 hours per processor, for a total one-time burden of 1600 hours. The estimated one-time cost associated with the processor tasks is \$64,000 (1600 hours x \$40). Each pharmacy will need to program to receive the code and print the response. Programming by the pharmacies (40 pharmacy software vendors) in order to receive the code by each pharmacy will be 10 hours, for a total of 400 hours. The estimated one-time cost associated with the processor tasks is \$16,000 (400 hours x \$40).

We estimated that the average time to process a coverage determination is 10 minutes (0.167 hours) and that the average number of coverage determination requests received by mail or secure website processed for each respondent (n=731) was 734. Requiring plan sponsors to process the information submitted in standardized coverage determination requests forms (§423.128(b)(7)(i)) is, therefore, estimated to result in an annual burden of 89,605 hours (731 entities x 734 contracts per entity x .167 hours per contract to process). At an estimated cost of \$40.00 per hour, the estimated total annual cost of this change is \$3.5 million. We estimated that processing coverage determination requests that are received by telephone (§423.128(d)) will take an average of 10 minutes (0.167 hours) per request and that entities (n=731) would process on average 944 coverage determination requests. This is estimated to result in an annual burden of 115,240 hours (731 entities x 944 determination requests per entity x 0.167 hours per determination request). At an estimated cost of \$40.00 per hour, the estimated total annual cost of this change is \$4.6 million (115,240 hours x \$40.00 per hour). We estimated that contacting entities (n=731) would distribute an average of 2,200 pharmacy notices.

Therefore, requiring plan sponsors to arrange with their network pharmacies to distribute pharmacy notices at the point-of-sale when prescriptions cannot be filled as written (§423.562(a)(3)) is estimated to result in an annual burden of 53,071 hours (2 minutes or 0.033 hours at point-of-sale x 731 contracts x 2200 pharmacy notices per contract). At an estimated cost of \$40.00 per hour, the estimated total annual cost of this change is \$2.1228 million.

		responde nts	respon ses	Burde n per respo nse	Annu al burd en hours	Hourly labor cost of reporti ng	Total labor cost	Tota l capit al costs	Total Cost
§423.128(b) (7)(i)	093 8- Ne w	731	536,55 4	0.167	89,60 5	40.00	3,584,1 80	0	3,584,2 00
§423.128(d)	093 8- Ne w	731	690,06 4	0.167	115,0 11	40.00	4,600,4 40	0	4,600,4 40
§423.562(a) (3)	093 8- Ne w	731 40 40	1,608,2 00 40 40	0.033 40 10	53,07 1 1,600 400	40.00 40.00 40.00	2,122,8 40 64,000 16,000	0 0 0	2,122,8 40 64,000 16,000

#### Voluntary de Minimis §423.70(f)

The burden associated with this requirement is the time and effort necessary for a Part D plan to submit data to us indicating its decision to volunteer to waive the de minimis amount. Since we will collect this information as part of an already established system, we estimate that annually, it will take an additional 10 minutes for plans to read the instructions, select an online check box, and submit the information. For purposes of estimating the burden, we assume that the de minimis amount will be \$1.00, and that all Part D plans with premiums within the de minimis amount over the regional LIS benchmark will volunteer to waive it. We estimate 150 Part D plans will qualify for de minimis in a given year. For 150 plans at 10 minutes each year, we estimate the total annual burden hours are to be 25. We assume an hourly wage of \$23.92 for a compliance officer, resulting in a total labor cost of \$598.

#### 13. Capital Costs

##### Uniform Exceptions and Appeals

Not applicable.

##### Voluntary de Minimis §423.70(f)

Not Applicable

#### 14. Cost to Federal Government

##### Uniform Exceptions and Appeals §423.562(a)(3)

Not applicable.

Voluntary de Minimis §423.70(f)

None

15. Changes to Burden

Not applicable.

16. Publication/Tabulation Dates

Uniform Exceptions and Appeals §423.562(a)(3)

Not applicable.

Voluntary de Minimis §423.70(f)

Not applicable.

17. Expiration Date

Uniform Exceptions and Appeals §423.562(a)(3)

This collection does not contain a data collection instrument.

Voluntary de Minimis §423.70(f)

Not applicable.

18. Certification Statement

Uniform Exceptions and Appeals §423.562(a)(3)

Not applicable.

Voluntary de Minimis §423.70(f)

Not applicable.