PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

May 29, 2015

Submitted via email to www.regulations.gov under CMS –10588

Centers for Medicare and Medicaid Services (CMS)
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number CMS-10558
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear CMS:

RE: Information Collection for Machine-Readable Data for Prescription Formulary Content

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the CMS's intention to collect information from the public (Document Identifier: CMS-10558 and CMS-10463). PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare and Medicaid. PCMA members are committed to providing low-cost, quality, safe and effective pharmacy benefit programs to our clients and their employees and policyholders.

A. Overall

Conceptually, PCMA supports facilitating consumer access to formulary information. We think this is a very important initiative and thus that it is critical that CMS should make sure that the requirements it is considering to achieve such transparency are realistic, consistent and reasonably achievable in the proposed timeframes. To achieve these goals, the clarity of what is being required and the development of the related technical aspects become paramount. PCMA realizes that this Paperwork Reduction Act (PRA) regulatory process may not be the typical vehicle as to which some of our comments should be directed. However, it is the process by which some of the critical determinants will be finalized and, thus, we use these comments to highlight the range of considerations which we believe need to be addressed to best achieve consumer access to formulary drug list information.

B. Comments on Information Collection for Machine-Readable Data for Prescription Formulary Content for FFM QHPs – Justification

1. Need and Legal Basis. (Page 1)

   It would be helpful to have clarification on some of the terms used here both as to the intended audience for the content sought to be collected as well as the intended information to be shared. Some statements in the PRA indicate that the intended users are "third-parties" or "software developers" or "developers" while others state that the focus is on "marketplace consumers" or "enrollees" as the users. Depending

on the intended user, the content of the data presented may vary. For example, terms aimed at a software developer may be more sophisticated than those geared to a marketplace consumer. We recommend that CMS clarify that consumers do not have access to these files on the issuer's websites. Consumers will not understand the information presented in this format (whether JSON or another format).

Likewise, we also are not clear on the terminology of exactly what information is being collected. In some places, the information to be collected is with respect to formularies but other places refer to formulary data, prescription formulary, formulary information or formulary drug list. The final CMS rule at §156.120(d)(i) requires plans to publish "a complete list of all covered drugs on its formulary drug list."

2. Duplication of Efforts. (Page 2)

The justification notes that "we anticipate no duplication of effort for issuers," noting that QHPs already provide URLs for consumer formularies as part of initial plan data collection. However, due to the distinction between formularies as referenced in this PRA and formulary drug lists currently submitted as part of the certification process, the request here appears to be for a different and much expanded effort. In other words, while the request may partially duplicate the current effort, there is a significant amount of new effort involved (see discussion under burden below).

3. Less Frequent Collection. (Page 3)

We concur that health insurance issuers should be required to update machine-readable formulary data "not less frequently than monthly." Because CMS has concluded this frequency sufficiently protects the critical interests of transparency and consumer engagement, we urge CMS to affirm that, as a general standard, consumer-facing formulary drug lists need not be updated more frequently than monthly and that implementation of formulary changes need not be delayed while awaiting updates to consumer-facing lists. The publication of this PRA notice creates ambiguity about whether this monthly update standard is intended to apply to all CMS-required consumer-facing drug lists[1] or only to the machine-readable formulary described here.

The dynamics of the prescription drug market and formulary management make it difficult for all publicly available formulary information to be updated in real-time, and, to the extent health insurance issuers delay implementing formulary changes until all publicly available formulary information is updated, those delays will generally be to the detriment of patients. To be clear, enrollees and providers can always contact the issuer to receive the most up-to-date information and many PBMs have dynamic search engines on their websites that provide fully up-to-date formulary information. However, in indicating that the machine-readable formulary information need be updated no more frequently than once a month, CMS acknowledges that it is not necessary for all publicly available formulary information to be completely up-to-date at all times. We request that CMS state clearly that this monthly update schedule also applies to formulary information required to be kept

[1] See HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10750, 10820 (Feb. 27, 2015).

up-to-date under 45 C.F.R. §156.122(d)(1), and that implementation of formulary changes need not be delayed until the next monthly update. Such synchronization will mitigate inconsistency by enabling software developers using the information to be aligned with the issuer's posted updates.

Formularies typically change due to the availability of a new drug. For example, if a generic version of a brand drug is newly available, the generic would be added to the formulary with a lower cost sharing than the corresponding brand drug. New drugs are not released on a regular schedule and drug releases are not predictable. Drug manufacturers do provide some advance notice of when they intend to release new drugs, which may be any day of a month, but those scheduled release dates frequently change due to litigation, regulatory concerns, production delays, or other issues. Manufacturer pricing information is also typically not released until the day the drug is available for sale. Patients could also be denied access to new branded drugs while awaiting the next update of the §156.122(d)(1) formulary.

While PBMs work as quickly as possible to update their formulary information when new drugs are released, there is inherently some lag between when formulary decisions are made and when each iteration of the formulary drug list is updated. Delaying the implementation of these types of formulary changes until the formulary required under §156.122(d)(1) can be updated would harm enrollees as they would need to continue paying the higher brand-level cost sharing even while a generic is available—or could be denied access to new drugs entirely.

We acknowledge that some formulary changes result not from the introduction of new drugs, but from a PBM's decision to impose additional limits, such as utilization management techniques, on the availability of an existing drug. However, these formulary changes are typically planned well in advance and are typically implemented in conjunction with the regular formulary update process. Thus, it is generally formulary changes that benefit enrollees that would be hindered if §156.122(d)(1) were interpreted to prohibit implementation of formulary changes until all publicly available formulary drug lists have been updated. We urge CMS to affirm that a monthly publication schedule is acceptable for both machine-readable formularies and the formulary drug lists required by §156.122(d)(1), and that implementation of formulary changes need not be delayed while awaiting publication of the monthly update.

4. Federal Register Outside Consultation. (Page 3)

The PRA notes that "CMS consulted with industry." However, our comments on the proposed rule noted that CMS needed to work closely with stakeholders on the machine-readable data requirements; yet, we have not been consulted.[2] We continue to reiterate that we would be pleased to provide input on acceptable technical specs for a "machine-readable file and format." Specifically, we again suggest that CMS provide an industry work group or other stakeholder vehicle to obtain this type of technical input. To the degree that CMS has or is consulting with industry, we

[2] We did file the attached comments on the proposed rule. (See discussion on pages 25-28.) We assume outside consultation envisions more than just the NPRM process; in any event, our comments requesting a 2017 effective data and consultation with the industry were not adopted.

request that CMS set forth in the final PRA which parties have been consulted and in what manner. We would like to better understand why PCMA and its members were not permitted a comparable opportunity to discuss our concerns with CMS.

5. Burden Estimates (Hours & Wages). (Pages 3-5)

These estimates substantially underestimate the burden involved. As discussed below, the JSON file format is not a common format in the health care industry, and we are not aware of any PBMs (or issuers) who have dealt with this file format. Thus, the use of this format will significantly increase the burden involved.

It is extremely difficult to provide accurate burden estimates until many of the questions raised by our comments are addressed. For example, if the list needs to include retail pharmacies, the burden in terms of hours and wages would be significantly increased, as this is not already commonplace in the market and as significant administrative, contractual, and legal issues would need to be addressed. Likewise, the burden may vary depending on the timing of implementation. It is not clear to us when the PRA collection requirements are to be finalized. Moreover, assuming they are finalized prior to the 2016 open enrollment in the Fall of 2015, it still remains unclear to us if the requirements apply at that time, or instead apply to "plan years beginning on or after January 1, 2016."

In any event, there will be significantly increased financial burden on issuers/PBMs if there is a short window between formal finalization and the date by which implementation is required. (This is due to unplanned and unbudgeted demands including for overtime, emergency IT builds, system testing and upgrade costs.)

Due to these uncertainties about what assumptions to make regarding the burdens, we received only two burden estimates.

a. Company One: The burden is just over $600,000 in development costs, $10,000 a year maintenance, and about a 12-month timeframe to build and implement.

b. Company Two: We estimate that the creation of this file will cost our organization between $100,000 - $250,000. This is an estimate and is subject to change based on final guidance. This estimate does not account for monthly maintenance costs.

Finally, the estimates ignore the fact that these burdens will have to be accounted for by issuers on the non-clinical side of the medical loss ratio (MLR) calculation, putting further financial pressure on the issuers as they seek to limit premium increases.

6. Publication/Tabulation Dates. (Page 5)

We also would appreciate information on how CMS intends to use the information it collects under this PRA. Will CMS post the updated versions as soon as it gets them from the issuer? How will it assure that the data used by the third-parties is as up-to-date as what is on the issuer website? If, in a given month, there are no changes to an issuer's formulary drug lists, will the URL still need to be updated for that month?

C. Comments on Developer Documentation – Appendix A

1. JSON. This states that all information must be described in the JSON file format. While we do not object to the use of this format, we note, as discussed above, that JSON is not commonly used in the health arena, so that the learning curve involved to implement this through JSON will be substantial. As an alternative to JSON, we would recommend any of the following formats: Medicare Plan Finder, .txt, or .csv. Unlike with JSON, there is wide industry experience with these other formats.

   We are also not aware to what extent state exchanges with drug list transparency requirements use JSON. Thus, we urge CMS to work with state exchanges that require similar information be submitted to establish a national standard for formatting and content rules.

2. Description. This states that the documentation will list plans and their corresponding formularies. As noted above, the regulatory requirement is for a drug list, not a formulary list. Terminology questions include:

   a. What is the definition of "formulary"? Is it "an array of drug lists"? Is that the same as "drug lists"?
   b. What is network sub-type? Please confirm that references to preferred and non-preferred in this section do not relate to the use of formularies.
   c. What is a formulary sub-type?
   d. Under drug tier, what is the definition of specialty?
   e. Under drug tier, what is "medical-service"? Drugs covered under the medical benefit of an issuer are not typically included in formulary drug lists.

3. Plan Schema.

   a. Pharmacy Type. Should there be reference to specialty pharmacy? How does this fit with requirement in the final rules that drugs that are limited to specialty pharmacy must be noted on the formulary?

   b. Mail Order. We are not clear as to the intent of the question, "does the formulary cover mail order?" The formulary is a list of drugs; mail order is a benefit feature.

   c. What is Cost Sharing Sub-type? We understood that formulary listings do not need to include cost shares, so we assume this is general tiering structures and not specific to certain drugs.[3]

   d. Drug Tier. The values provided for drug tier are not consistent with how drug tier information is typically submitted. Drug tier information is commonly denoted with numeric values (e.g. Tier 1, Tier 2). We would recommend that the tiers be removed from the schema, but if they are retained, we recommend that the values be changed to align with how this information is submitted in other files.

[3] See 80 Fed. Reg. 10819, "We are not requiring detailed cost-sharing information."

4. Provider Schema.

    a. Pharmacy Exclusion. We assume that pharmacies are not providers and ask CMS to confirm this assumption. For purposes of this data collection, there is no practical way to include pharmacies by January 1, 2016.

    b. Rxnorm ID. The information to be submitted here is intended to be a list of drugs and the plans that cover them. However, it is not clear to us if the format is intended to capture only drugs counted towards the Essential Health Benefits (EHB) benchmark, or to capture an entire formulary. EHB covered drugs are the drugs that were submitted by issuers on their prescription drug template during the QHP submission process. Examples of drugs that would not be captured under the EHB only approach includes drugs that are new to market and many OTCs. One of our members reports that on average, these submissions were less than 10,000 drugs. Yet, covered drugs on a formulary file can range above 50,000 drugs or more. Creating a formulary guide based on a full formulary file will take a much greater level of effort, so PCMA would strongly recommend that CMS clarify that this exercise is intended to capture only the EHB drugs.

    c. Plan ID. The inclusion of the HIOS-generated Plan ID on this table presents a great deal of complexity. PBMs do not have the HIOS IDs of their clients (the issuers) so they will have to be able to crosswalk each HIOS ID to the applicable plan/drug information into their systems, which will be an extremely burdensome undertaking.

5. Drug Schema. This states that the document "contains a list of drugs and the plans that cover them." This seems to be a more accurate description and we suggest this phrasing be included in lieu of references to formulary listings. We also strongly urge that CMS confirm that plans do not have to include all formulations of drugs on the formulary. If CMS intends to require all such formulations, it will not only significantly increase the burden detailed above, but also, we will have a long list of questions on how to achieve this obligation, as it is not common industry practice.

6. PA/ST/QL.

    We recommend deletion of quantity limits, as there is such a large range of what can be in place due to the drug safety considerations.

D. Timing Considerations and Options

1. Extension. As noted above, PCMA supports this initiative. We want to make sure that it achieves the goals of transparency and consumer access. We are very concerned as to the speed with which this is likely to be rolled out and, thus, we seek a delay in effective date until 2017. This is what we asked in our comments. Frankly, we just do not see the various stakeholders being able to have the current construct ready for the annual enrollment with a January 1, 2016 effective date.

a. By the time the PRA process is over and final specs are approved and published, it will be late summer at earliest.

b. Due to all of the development needed to support implementation, it is not clear how this could be achieved for annual enrollment with a January 2016 effective date.

2. Alternatives. In light of the issues noted in these comments with respect to barriers to effective implementation of this collection effort for 2016, we urge CMS/CCIIO to consider a range of alternative approaches.

    a. We request that 2016 be treated as a trial or "soft rollout" year. This would allow all stakeholders to work out the regulatory infrastructure, administrative and other issues so that meaningful access for consumers to formulary drug lists can be achieved. Simply put, we want to get this undertaking accomplished, but neither we nor CMS is ready for prime time on January 1, 2016. We urge that CMS treat 2016 as a transition period.

    b. CMS could pilot this initiative and see how it works in a few states for formulary drugs lists. Based on that experience, it could finalize a set of machine-readable data specs for 2017.

    c. Another alternative would be to allow issuers to format the lists of formulary drugs the same as is done for the QHP submission, create a file format, and allow that format to be used (true non-duplication of effort). At the same time, CMS could undertake a pilot as well.

3. Good Faith Compliance. If CMS insists on full implementation for 2016, then a good faith compliance standard should be used. If an issuer could not produce the complete submission, it could use best efforts for 2016 with the understanding that full compliance once all the relevant details, including those needed as noted above are provided, would be expected for 2017.

We appreciate the opportunity to comment and we urge CMS to consider PCMA's recommendations as set forth above.

Sincerely,

Wendy Krasner

Wendy Krasner
Vice President – Regulatory Affairs

Attachment