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May 29, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–10558
Room C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

SUBJECT: CMS–10558 Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs – AHIP Comments

Dear Mr. Slavitt:

We are writing on behalf of America's Health Insurance Plans (AHIP) to offer comments in response to the Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) Information Request related to the machine readable data for provider network and prescription formulary, published in the *Federal Register* (80 FR 16687) on March 30, 2015, and the subsequent detailed information posted on the CMS Paperwork Reduction Act (PRA) website. AHIP is the national association representing health insurance plans that provide coverage to more than 200 million Americans.

AHIP recognizes the critical importance of consumers having the ability and confidence to select a health plan based on accurate information about whether their health care providers participate in a health plan's network and whether their prescription drugs are included on plan formularies. We also recognize the importance of consumers effectively using their benefits throughout year and making informed healthcare choices. With those key goals in mind, AHIP supports ensuring consumer access to comprehensive, accurate and up-to-date information on health plan provider directories and drug formularies. We look forward to working with you to implement solutions that are both workable and benefit consumers.

To achieve this for the 2016 open enrollment period, our comments recommend a streamlined data structure that will still provide consumers with key information to assist their decision making while reducing the opportunity for errors. The data presented is designed to support answering two simple consumer questions: "In which QHPs does Dr. X participate in?" and "Which QHPs have drug X and drug Y on formulary?"

To support these use cases, for year one, we recommend the data files focus on those two questions and not include provider and prescription drug cost-sharing information. By including cost sharing information, CMS would add significant complexity and require additional data to accurately display each plan's deductibles, co-payments, co-insurance, provider network tiers as well as prescription drug formulary tiers. Keeping the files as simple as possible in year one will ensure a workable approach for health plans while still providing meaningful information for potential enrollees.

Moreover, we are challenged by extremely short implementation timeframes for a new data requirement. It is important that CMS' finalizes the data standard and implementation approach as soon as possible so plans can have ample time to produce and test their files prior to the start of the 2016 open enrollment with the greatest degree of confidence that the data can be correctly displayed by CMS on healthcare.gov and by third party developers. In addition to a finalized schema, health plan technical experts are in need of additional information on how various APIs will connect to plan websites to access the data on a regular basis and more detailed data definitions. Without adequate development and testing time, we are concerned that the information presented to consumers will fall short of expectations and result in diminished consumer confidence in the program.

Below we provide general comments on the proposed data standard and data usage considerations.

Data Standard

The developer document outlines three potential files health plans would be required to post which we offer detailed comments below:

- Plan File – List of Health plans and their corresponding network of providers and formularies
- Provider File - List of providers and facilities
- Formulary File – List of prescription drugs on a health plan's formulary

In general, we support the use of the JSON standard and recommend that health plans post the JSON files to their website and provide CMS with a link to the posted information. Such an approach negates the need to send updated data to CMS every time the data is changed, which will be more efficient for plans as well as CMS. Where State-based exchanges require plans to submit similar information, we recommend that CMS work with state based exchanges to implement a national standard for all FFM and interested SBMs to ensure consistent formatting and content rules.

Plan File

We strongly recommend that CMS reduce the number of data elements in the plan file to support a simpler use case. We are concerned about the ability for third parties to accurately represent a QHP's benefit design and cost sharing structure with the information included in the plan file. This may result in vendors producing plan snapshots with inaccurate or incomplete plan descriptions, which could actually increase consumer confusion. Currently, even with a more robust set of data, Plan Compare within Healthcare.gov does not accurately represent more unique or innovative plan designs that contain multiple tiers or unique deductible approaches.

Further, we recommend CMS continue the current practice of posting public use files with the detailed plan information. This will allow third party vendors to map the data included in the JSON files to the public use files. Given QHP benefit structures do not change throughout the year unless there are minor data corrections (unlike provider and formulary information), we recommend CMS use this approach to make plan data available to third parties to ensure that a complete representation of plan design and cost sharing is displayed for potential enrollees.

We recommend that the plan JSON file only include the following data fields:

- Plan_id_type
- Plan_id
- Marketing_name
- Summary_url: We recommend this is renamed SBC_url so it is clear that this is referring to the SBC link and not a page with general information.
- Marketing_url: We recommend this is renamed to the brochure_url so it is clear that is referring to the URL for the plan brochure. We recommend this is changed to a required field.
- Last_updated_on
- New Fields: Along with two new data fields for a link to the plan's provider directory and online formulary which are discussed below.

As part of the reduced set of data elements, we recommend that CMS remove the following fields:

- **Plan Contact Email address for error reporting**: For year one, it would be difficult for health plans to establish new processes to accept comments on data issues in the machine readable files from third party vendors which would need to be validated and processed in a timely manner. For concerns about the coverage of specific prescription drugs or prescription drug formulations, potential enrollees and enrollees can contact their health plan for specific information or file an appeal if necessary.
- **Network Tier**: For year one, the tools should not display separate provider network tiers (where applicable). Plans with multiple tiered networks should include all providers in their

network(s) as part of their machine readable file. Information about network tiers can be provided in the health plan online provider directory. As an alternative, if a plan includes a network with multiple tiers, a simple Yes/No flag can be added to the JSON file so data users know to check the specific provider's tier in the health plan's online directory.

- **Cost sharing sub-type:** The search tools should focus on simple questions such as, "Which plans have drug X on formulary?" and should not make any detailed analysis around cost sharing. The information on pharmacy drug pricing will be provided elsewhere in Healthcare.gov and part of the plan's description, plan brochure and Summary of Benefits and Coverage. Careful consideration should be given regarding the need to display the cost-sharing of the cost-sharing reduction plans given it may vary depending on the eligibility. Thus we recommend for year one the file not include information on pharmacy types and drug co-pay and co-insurance amounts which will be available both in the premium estimation tool as well as healthcare.gov Plan Finder.

Given the more detailed information in the plan's online provider directory and online prescription drug lists, when data from the machine readable files are displayed we recommend that direct links to health plan websites be included. Specifically, we recommend the addition of the following new fields:

- **Provider Directory URL:** The URL that directs the consumer to the provider directory for the specific plan or plan variation and that is included in the QHP filing.
- **Formulary URL:** The URL that directs the consumer to the health plan list of covered prescription drugs for the specific plan or plan variation and that is included in the QHP filing.

Provider File

Our recommendations for revisions to the provider file are designed to focus on the simplest data use cases. While more detailed data may be important to add in future years, for the first year of implementation the focus should be how to ensure data can be accurately represented across plans. We recommend the provider file data elements are limited to the minimum necessary to answer the basic question: "Which QHPs does Dr. X participate in?" We offer the following comments on the data elements in the provider file:

- **Address:** We recommend the deletion of the duplicate address field and revise to Address_1 and Address_2. For providers with multiple locations each location would be listed as a separate and unique provider. Examples should be provided to show how providers with multiple locations should be represented as it appears that Address_2 was designed to represent a second address line (e.g. suite number) and not a second location.
- **Type:** We recommend this field is renamed to Provider_type so it is not confused with the plan_id_type incuded in the plans.JSON file.

- **Middle Name:** This is listed as a required field. Requiring a middle name represents a cultural bias because not all practitioners will have one. The field should be optional or there should be a standardized "filler" to denote that the field is intentionally blank.
- **Suffix:** This field should be used to express a formal demographic suffix (e.g., JR) and not provider credential (e.g., MD, DO, etc.). If provider credential is needed, it should be included as a separate field.
- **Phone:** For simplicity, we recommend that in year one, only one primary phone number be provided for each provider. For providers with multiple locations and thus multiple phone numbers each location would be listed as a separate and unique provider.
- **Specialty Type:** Many plans do not use a common data dictionary or standard data definition for specialty type. We recommend that the specialty type should use the Healthcare Provider Taxonomy Code Set which is available from the Washington Publishing Company (www.wpc-edi.com) and is maintained by the National Uniform Claim Committee (www.nucc.org). The code set is updated twice a year, with the updates being effective April 1 and October 1 of each year. The code set is used by CMS in the NPI registration system and includes an expansive set of specialists.
- **Accepting Patients:**
    - While we recognize that this information is required to be included in the health plan provider directory, we recommend it not be included in the JSON file for year one or made an optional field. This information can change frequently – weekly, monthly, quarterly, etc depending on patients moving in and out of a physician practice due to relocation, death, etc. Even if the directory information was accurate at the time of enrollment, because of the limited open enrollment period, it could be inaccurate by the time many consumers seeks health care services from the provider. This information should be verified directly from the provider.
    - Based on consumer experiences from the first year of implementation, CMS can revisit the inclusion of this field for future years. At a minimum if this element remains in the schema, we recommend there is a mandatory disclaimer regarding the potential inaccuracy of this information for year one and it is changed to "accepting new patients". For the first year the data field could indicate that the consumer call provider to verify or is limited to primary care providers.
- **Facility Type:** We recommend this field is renamed as facility specialty and the same code set that is used for provider specialty is used here (Healthcare Provider Taxonomy Code Set).
- **New Fields:**
    - Primary Care Provider: We recommend a new optional field is added to the schema, consistent with current practices in health plan directories today to indicate whether a particular provider is a Primary Care Provider. This optional field can be listed as Yes/No.

- Last_updated_on: In addition to including a last updated date in the plan file, we recommend it is also included in the provider file to support uses cases where plans are only updating a portion of the three JSON files.
- Future Effective Date: An optional field that health plans could use to include specific providers that will be soon added to the network.

Drug File

Our recommendations for revisions to the prescription drug file are designed to focus on the simplest data use cases. While more detailed data may be important to add in future years, for the first year of implementation the focus should be ensuring a limited data set can be accurately represented across plans. We recommend the drug file data elements are limited to the minimum necessary to answer the basic question: "Which plans have drug X and drug Y on formulary?" More complex use cases like "Which plan has drug X with the lowest co-pay/co-insurance (i.e., lowest tier)?" can be added in future years. The phasing in of such complex data uses over time is consistent with the approach used for the Medicare Part D Plan Finder.

In general, the basic information proposed in the prescription drug file will be helpful for consumers. We support the use of the RxCUI, and yes/no information on whether a particular drug requires step-therapy or prior authorization. Wherever possible the submission of the drug file should leverage existing data formats for the benchmark submission, assessment counts, the QHP prescription drug template or Medicare Part D. It will be important that all plans use the same RxCUI CMS defined or provided reference source and release to ensure an accurate comparison across plans (similar to current practice for Part D today). We recommend that for this year's submission CMS use the same source and version that is required for the prescription drug template (November 3, 2014, full monthly release of RxNorm) and that that version be updated on, preferably, a monthly basis to ensure that monthly updates for the posted machine readable formulary remain in sync with changes or new drugs introduced to the market over the course of the year.

In addition to a defined source for RxCUIs that is regularly updated on a monthly basis, we request that CMS provide guidance regarding submission of drugs for which an RxCUI is not yet provided or defined. Specifically, we request that CMS provide a default value to ensure that, at a minimum, the formulary items will load and can be displayed for consumers.

As part of a narrower set of data elements, we recommend the following data elements are removed:

- **Drug-name:** This is already covered by the RxCUI and is duplicative. Vendors using the data can access the full RxCUI list mapping the codes to the specific drug name/formulation. Duplicative information creates an opportunity for both confusion and errors.

- **Quantity Limits:** For simplicity and given that a variety of quantity limits can be in place to ensure drug safety, we recommend deletion of this element. This information will be available to consumers in each health plan's online prescription drug list.
- **Drug Tiers:** For year one we recommend that the JSON file not contain information on which drug tier each particular drug is in along with associated cost sharing. If this field is not removed, CMS needs to provide a reference data set with allowable values to ensure data consistency across issuers.

While some issuers may have highly tailored formularies that vary from one plan to another (14-digit QHP ID), many issuers have formularies that are consistent across multiple product lines. It is important that the machine readable file maintains the flexibility for issuers to accurately reflect their formulary and drug list information in a streamlined manner. The health plan JSON file requires that for each QHP (14-digit QHP ID), an issuer list all formulary information associated with that QHP. This would be duplicative for issuers who have the same formulary across multiple QHPs or products. The drugs JSON file also lists the 14-digit QHP ID for every plan associated with an RxCUI in the drug list. However, issuers do not directly associate a prescription drug with a particular QHP, instead drugs are associated with a formulary, which is then assigned to a health plan or product. Additionally, failing to use the industry standard formulary ID would put additional burden on issuers who use a Pharmacy Benefit Manager (PBM), as the PBM would not have the plan-level information.

To address these issues, we recommend that the machine readable file include a Formulary ID data element to organize drug information by formulary. Thus, in the plans JSON file, formulary information should be organized by Formulary ID. Each health plan could then be associated with that ID, rather than re-listing information for every plan that uses that formulary. Similarly, in the prescription drug JSON file, drug information should be sorted by formulary (which is then linked to a plan in the plan JSON file) rather than listing every plan ID that offers a prescription drug. This approach would allow issuers to more accurately reflect drug information and would be consistent with the way this data is collected in the QHP Prescription Drug template. For issuers with PBMs, it would allow the PBM to develop the file without requiring additional information from the issuer. It would also be an exponential reduction in the size of the file.

Finally, we recommend the drug file also include a "Last_updated_on" field. In addition to including a last updated date in the plan file, we recommend it is also included in both the provider and drug file to support uses cases where plans are only updating some of the three required files.

Alternate Data Formats
We note that for the drug file, adequate existing national machine readable standards are already in place (e.g. benchmark submission, QHP prescription drug template or the part D standard).

Due to the short timelines remaining prior to open enrollment CMS should permit the continued use of these existing standards for the 2016 files with a plan to move to JSON for the 2017 files. Alternatively, CMS could enhance tools already provided on the HIOS website that allow for evaluation and loading of current national machine readable standards to also export out the desired JSON format. This would have the benefit of supporting health plan's move to JSON on a more aggressive timeline as well as providing a bridge and encouragement for SBMs to support the same JSON format as the FFMs and ease any future changes to the JSON format.

Data Considerations

Universe of Providers, Drugs and Plans
For the first year of implementation we offer the following recommendations to clarify which providers, drugs and plans are included in the posted files. Within the subset of required providers, we appreciate the flexibility given for plans to determine the universe of their providers to be included in the JSON file. Plans may choose not to display providers who have contracted with a facility (subcontractors to the issuer) where the member would not have their choice of provider (e.g., hospitals, outpatient surgical centers, and ambulatory surgical centers). For these facility types, we recommend plans only list the facility in the network. The member cannot choose their provider in these settings and so it would be confusing or misleading to require issuers to include all providers contracted within the facility (e.g., pathologists, radiologists, anesthesiologists, or ER physicians).

We recommend that JSON files should include only providers in the state for which they are offering coverage, as well as any providers in contiguous states from which enrollees may access services. Inclusion of additional providers should be at the option of the plan.

For the list of facilities, we recommend that plans are not required to include pharmacies or laboratories. All of these data sets are typically maintained by separate entities and it would be challenging for health plans to integrate this data into a common file by the fall. In addition, this information would be available on each health plan's website.

Regarding which drug formulations are included, we recommend that CMS, consistent with the flexibility afforded to plans in the 2016 Payment Notice, permit plans to not include all formulations of drugs on the formulary.[1] We recommend that plans have the flexibility regarding how to populate the non-preferred tiers of an open formulary. We suggest that 'default' drugs should be sufficient to avoid listing all the thousands of non-preferred drugs.

[1] See 80 FR 10819 which indicates a "complete" formulary does not have to list every covered formulation for each covered drug.

Finally, for the plan file CMS should clarify which plans should be posted during the open enrollment period. We recommend that health plans should only display the 2016 plan offerings and not the 2015 plans that would be available to consumers with a special enrollment period. This same approach should also apply to the list of providers and drugs. Plans should include their lists as of January 1, 2016 to ensure simplicity and reduce the opportunity for confusion regarding 2015 and 2016 offerings.

Data Update Timeline
CMS should allow plans to establish their own machine readable update schedule so that data is updated no less than monthly. The last updated date field in the plans file in the schema can support this flexibility but would need to be added to the provider and drugs JSON file. The same update standard should also apply to the drug list, even though the recent changes in the 2016 Payment Notice requires plans to update their online drug list simultaneously with formulary changes. We recommend that CMS provide its data-pull down schedule so issuers, if they choose, can align their data posting schedule accordingly and that when issuers post changes they post a complete new file and not just a change file.

Availability of Weblinks
The Developer Documentation indicates that organizations must post the JSON files on their websites accessible to the public. As part of the final PRA package (or as soon as possible) CMS must indicate the date by which live links must be available. Given the very short timelines, we recommend that CMS not require the availability of live links before October 15, 2015. The implementation timeframe for 2015 for preparing machine readable files in CMS required formats may not be realistically achievable for some organizations that do not have systems capable of compiling such information. We read 45 CFR 156.800(c) to apply to good faith efforts to meet the requirements relating to any pre-2016 data submissions under to 45 CFR 156.122(d) and 45 CFR 156.230(c). In such an instance, we request that CMS include a link to the organizations' own website in order to allow consumers to view formulary lists and provider directories of the organization.

We recommend that additional guidance specify the level of the data files to be at the issuer level.

Testing
If Healthcare.gov will utilize the JSON files to support consumer searches, we strongly recommend that plans are afforded the ability to preview how their data is displayed as part of any consumer tools prior to November 1st so that they can make any necessary data corrections.

Data Definitions & Data Accuracy
We note that most of the fields don't have a data definition. This could pose challenges if health plans define key fields differently. We recommend that CMS provide general definitions and

reference national recognized data definitions for all of the data elements. For example, the final specification should include information on which address should be provided, a definition of specialty and the specific taxonomy that should be used.

Testing may demonstrate the need to also include audit, balance and controls within each data standard. We recommend the standard includes control totals in each file (e.g., this file or file section contains three formularies) to ensure the data is properly loaded and displayed.

Development of a CMS Disclaimer – User Agreement
Currently, when downloading public use files, CMS includes a *CMS Disclaimer – User Agreement* which details the sources and nature of the data, including potential limitations, and specifies the responsibility of the data user in regard to the processing and understanding of the data files. Similarly, web-based entities are required to sign a data use agreement with CMS. We recommend that CMS develop a Disclaimer/User Agreement that all third party vendors who are accessing the weblinks of health plan files are required to sign. The Agreement should address limitations on the use of the data, require posting of common disclaimer language wherever data is posted (see below), legal language (e.g., information is best available/ not binding) and considerations for when data is aggregated. The agreement should include a hold harmless provision that prevents the issuer from being liable for mistakes on the third party site. We request that CMS make public for comment the proposed draft Disclaimer-User Agreement and to allow the data providers the opportunity to comment on this Agreement.

It will be important for CMS to create a registry system that contains the contact information of the third-party vendors with whom data use agreements will be signed. Issuers should be able to access this information in case of errors. The data should be secured on issuer websites to limit use by unknown parties. Only third parties or other members of the public who sign the data use agreement should have access to the files.

Consumer Disclaimers
We recommend that CMS develop standard disclaimer language that all vendors displaying provider information should be required to include. The provider directory disclaimer should address:

- Importance of searching the correct plan network as not all providers may participate in all of a company's network products;
- Importance of consumers always confirming network participation with their provider and health plan given the possibility of changes throughout the plan year;
- That information is based on plans' reasonable efforts to provide accurate and up-to-date data as of the date specified (i.e., the information is current as of X date);
- Consumers should always refer to their health plan coverage documents regarding prior-authorization, prior-notification and referrals before making an appointment with a provider;

- Because data is subject to change, health plans are not liable for any losses, damages, or non-covered charges as a result of using this tool or receiving care from a provider listed in the tool; and
- Health plans' website provider locator tools may include information that is updated more frequently.

Sample Disclaimer: Provider information contained in this directory is updated on a monthly basis. Providers may join or leave a carrier's network at different points throughout the year. Also, not all providers participate in all networks. If you have selected a provider but not completed your plan selection, the directory may be updated and, you will have to re-establish your filters to continue to browse plans. Note that you may be required to obtain a referral or pre-authorization to see a provider even if they are in your selected network. Additionally, you may be required to receive a pre-authorization to receive medications. Please check with your carrier before scheduling an appointment or receiving services to confirm whether a provider is in network or requires a referral or pre-authorization. For additional network questions, we suggest you reach out to the carrier for more details.

The prescription drug list disclaimer should address:

- The importance of consumers talking to their doctor about prescribing formulary medications, which may help reduce out-of-pocket costs for the consumer. A plan's formulary should be used to help consumers and their doctors in selecting an appropriate medication.
- Consumers should be encouraged to show their formulary drug lists to their physicians and pharmacists. Physicians are encouraged to prescribe drugs on this list, when right for the enrollee. However decisions regarding therapy and treatment are always between members and their physician.
- That the presence of a drug on the plan's formulary does not guarantee that an enrollee will be prescribed that drug by his or her prescribing provider for a particular medical condition.
- That information is based on plans' reasonable efforts to provide accurate and up-to-date date as of the date specified;
- Consumers should always follow health plan rules regarding prior-authorization and other requirements prior to filling a prescription;
- Because data is subject to change, health plans are not liable for any losses, damages, or non-covered charges as a result of using this tool or receiving a drug listed on the tool; and
- Health plans' website formulary tools may include information that is updated more frequently.

Thank you for the opportunity to provide comments. Please do not hesitate to contact me if you have any questions at 202-861-1491 or jthornton@ahip.org.

Sincerely,

Jeanette Thornton
Senior Vice President, Health Plan Operations and Strategy