BlueCross BlueShield Association

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4800
www.BCBS.com

May 29, 2014

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
7500 Security Boulevard, Baltimore,
Maryland 21244–1850

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

Dear Mr. Slavitt:

The Blue Cross Blue Shield Association – a national federation of 37 independent, community-based and locally-operated Blue Cross and Blue Shield companies ("Plans") that collectively provide healthcare coverage for nearly 105 million members, or one-in-three Americans – is pleased to provide comments on "Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs," as issued in the *Federal Register* on March 30, 2015 (80 Fed.Reg.16687).

We agree it is essential to give consumers easily discernible and transparent information about provider directory and formulary information. Plans already provide sophisticated electronic directories that give consumers a variety of detailed search functionalities. However, we are concerned that the proposed standards for qualified health plan (QHP) issuers to submit provider and formulary data in a machine-readable format to the Department of Health and Human Services (HHS), and for posting on issuer websites, could inadvertently lead to more, not less, consumer confusion because the standards do not fully take into account (1) the enormous challenges to maintaining and improving the accuracy and timeliness of data; (2) the lack of standardized data definitions; (3) the interplay between provider and formulary data and the benefit designs and coverage rules of the associated QHPs; (4) the highly compressed compliance and testing timelines leading up to open enrollment for 2016; and (5) the potential for even greater inaccuracies when third party software developers are given carte blanche with issuers' information.

Therefore, we recommend focusing this year's efforts on meeting the two use cases of overriding importance to consumers: (1) In which QHPs is a particular provider participating (i.e., in

network); and (2) In which QHPs is a particular drug covered (i.e., in formulary) by focusing on the essentials by:

- Modifying plans.json, providers.json, and drugs.json – generally by removing data elements, but in some cases adding data elements – to provide the minimum data necessary for the two overriding use cases, and to minimize inconsistencies in information across issuers.

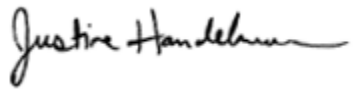
- Clarifying that access to JSON files on issuers' websites is only through pre-arranged security keys or log-in procedures.

- Establishing Data Use Agreement requirements with third party software developers so that any tools they develop do not confuse consumers by providing different information from that which is in issuers' electronic directories, or in the new search field CMS plans to add to the healthcare.gov learning window.

- Encouraging consumers through disclaimers to check and take advantage of the search functionalities on issuers' websites, and always to check directly with a provider to verify information.

Our detailed recommendations follow. Thank you for your consideration of our comments. If you have questions about comments related to the provider directories, please contact Joel Slackman (joel.slackman@bcbsa.com or 202.626.8614); prescription formularies, please contact Mona Mahmoud (mona.mahmoud@bcbsa.com or 202.626.4838).

Sincerely,



Justine Handelman
Vice President, Legislative and Regulatory Policy

DETAILED COMMENTS ON INFORMATION COLLECTION FOR MACHINE READABLE DATA FOR PROVIDER NETWORK AND PRESCRIPTION FORMULARY CONTENT FOR FFM QHPS

Our detailed comments follow the organization of the Developer Documentation in Appendix A.

JSON

Issue. All information must be described in the JSON file format. CMS notes it is quickly becoming the de facto standard for shuttling data across the internet, fueled primarily by the rise of mobile and APIs. However, issuers will need time to extract data, reprogram systems, and complete internal testing – a minimum of 8 to 12 weeks after CMS finalizes the specifications. Presumably, issuers must publish JSON files by November 1, 2015, the start of the 2016 open enrollment period.

Recommendation. CMS should complete analysis, design, development, and external testing of JSON files and the interfaces with the new search field in the healthcare.gov learning window by no later than the end of August.

Rationale. Time is tight to implement the JSON files and new search capabilities: indeed, some issuers may find even 8 weeks between finalizing specifications and publishing files insufficient, and will have to carry out parallel development (i.e., prepare for different development paths by creating and testing variants), which introduces a complexity that will raise costs and be challenging to manage. The tight timing argues in favor of the two simple use cases recommended in the cover letter, and also in favor of putting limits on third party software developers (as discussed below).

PUBLIC DISCOVERABILITY

Issue. 45 CFR 156.230(c), Increasing consumer transparency, directs a QHP issuer in a Federally-facilitated Exchange to make provider directory information available in an HHS specified format on its Web site. "HHS specified format" presumably refers to the machine-readable files and formats discussed in the Preamble to the 2016 Notice of Benefit and Payment Parameter. Section B2 of "The Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs (CMS-10558) states: We expect software developers to access this information to create tools to help enrollees better understand the availability of drugs and providers in a specific plan.

Recommendation. Clarify that only software developers who have a security key or log-in privileges consistent with a data use agreement (DUA) – see recommendation below – will have access to information in the JSON files.

Rationale. CMS's primary rationale for making machine-readable data available is to provide the opportunity for third parties to create resources that aggregate information on different plans, not for

general access by the public. As discussed below, establishing DUAs that put parameters around access by third parties will prevent a "wild west" of tools that would risk considerable consumer confusion. Providing a secure mechanism for accessing the information will discourage haphazard and ill-conceived tools, i.e. protecting consumers from bad apps, similar to how Apple has a tightly controlled environment to ensure quality control. This is not an opportunity to randomly experiment with technology when consumer health and choice is at stake. There is also an additional burden on issuers needed to test with the external developers to ensure that the developer is accurately displaying information. Further, as recommended below, CMS should ensure adequate disclaimers on the third party tool that the consumer should check their provider directly on issuer's site prior to making a purchasing decision,

HEALTH PLANS – PLANS.JSON

Provider Network Tier

Issue. The schema includes a field for Network Tier (applies to providers, e.g., preferred, non-preferred).

Recommendation. Remove this field from plans.json. Make clear in disclaimer (see recommendation below) that network tier and drug tier information are best examined on the health plan's website.

Rationale. Including this field will do little to improve transparency, will increase operational complexities, and will add to, not lessen, consumer confusion. The tier of a provider has no intrinsic meaning outside the context of the QHP's benefit design; tools developed by third parties and CMS would not provide consumers the context they need to interpret these elements appropriately. For example, cost-sharing for a provider in one network's Tier 1 could be the same as, or higher, than the cost-sharing for the same provider in another network's Tier 2.

Drug Tier and Cost-Sharing

Issue. The schema includes fields for Drug Tier (tier for formulary) and Cost Sharing (array of cost sharing values, as defined by specified cost-sharing sub-types).

Recommendation. Remove these fields from plans.json.

Rationale. Including these fields will do little to improve transparency, increase operational complexities, and engender consumer confusion. Furthermore, this data field outside the context of the benefit design may be confusing and misleading to members. For example, some plans may label their preferred and Non-preferred brand-name tiers as Tier 2 and Tier 3, while another plan may add a "value generic" tier and call them Tier 3 and Tier 4, appearing to some members as a higher priced tier.

Plan Contact

Issue. The schema includes a field for a Plan contact email address so that developers/public can report mistakes in the network and formulary data.

Recommendation. Remove this field from plans.json.

Rationale. This field is unnecessary and raises problematic issues. First, the reference to the public is confusing because, as discussed above, CMS appears to want software developers specifically, not the public in general, to have access to the JSON files. Plans already have mechanisms (electronic, paper, and telephonic) for their members and contracted providers to provide updates and to verify such information. Second, giving developers an email to report mistakes raises operational challenges in that issuers will have to keep track of and store email reported mistakes for multiple QHP products/networks. More important, including this field establishes a tacit expectation that issuers will act on the emailed reports from parties with which they have no relationship. As no issuer will take a reported mistake on faith, issuers will need to carry out due diligence to determine whether the reported mistake(s) are truly a mistakes or artifacts of the processes used by the third party developer. This time consuming and costly collection and verification process will significantly increase the burden that issuers already have for maintaining the issuer's provider directory and formularies for enrollees.

PROVIDERS – PROVIDERS.JSON

Providers Included—Individuals

Issue. Providers.JSON contains a list of providers and the plans that cover their services. However, certain types of individual providers, specifically hospital-based specialists (e.g., a provider, such as an anesthesiologist, that only sees patients as a result of their being admitted or directed to the hospital) generally do not appear in the provider directory, which creates ambiguity over including names of hospital-based providers in providers.json.

Recommendation. Clarify that issuers need not include the names of hospital-based providers in the JSON files.

Rationale. Presumably, consumers care about providers who they can see or be referred to directly from another physician or organization: hospital-based providers who see patients only as a result of patients being admitted or directed to a hospital would not seem to be the basis for consumers' selection of a plan.

Moreover, issuers often do not credential hospital-based providers – credentialing is a prerequisite for being included in the provider directory – instead requiring that the hospital has credentialed the provider. This is, for example, the standard under NCQA accreditation, which requires plans to credential all practitioners with whom they have an "independent relationship," such as primary care physicians, non-

hospital-based specialists and behavioral healthcare providers, among others. According to NCQA, for an anesthesiologist who practices at a hospital and only consults on surgeries, an NCQA Accredited health plan would be required to have a policy ensuring the hospital has credentialed the practitioner. If the anesthesiologist consults on surgeries, practices at a separate pain clinic and is listed on the health plan's provider directory, the health plan would need to credential the physician.

Providers Included—Facilities

Issue. Issuers typically contract with facilities that do not have direct relationships with members, such as pathology labs.

Recommendation. Clarify that issuers need not include the names of facilities that establish relationships only with providers, not patients, such as labs performing pathology services.

Rationale. Same as for excluding hospital-based specialists.

NPI

Issue. The schema for individuals includes a field for the National Provider Identifier (NPI). Supporting documentation does not explain the reason for including NPI.

Recommendation. Clarify that NPI is to be used – whether by CMS in the new search field on the healthcare.gov learning window or by third-party software developers – only to match names of providers across issuers (e.g., is J. Smith in one QHP the same as James Smith in another).

Rationale. Any search aggregator will need to rely to some degree on NPI for name matching. However, the utilization of NPIs is not perfect, since providers may have multiple NPIs or submit bills under an institutional NPI (one more reason why a disclaimer will be so important). However, using NPI to validate or indicate other information, such as location or specialty, could introduce discrepancies between true information contained in an issuer's directory and information contained in a third party's application. For example, a third party may use information specialty related to the NPI to override specialty in an issuer's provider directory (e.g., if the provider has been credentialed as a general surgeon for purposes of network participation, but the third party scrubs the data by substituting the provider's self-reported information in the NPI that the provider specializes in plastic surgery).

Name

Issue. The schema for individuals includes middle name as a field that is "always required."

Recommendation. Make this an option field or develop a standardized filler denoting that the field is intentionally blank.

Rationale. Not all providers have or use a middle name.

Address

Issue. The schema for individuals seems to allow for listing the address of only one practice location. However, providers often practice in multiple locations. For example, a provider may see patients in one location during the first half of the week but alternate to another location to see patients for the second half of the week. One location may be primary, but there are no standardized criteria for determining which location is primary.

Recommendation. Revise the schema to allow issuers to add as many addresses as needed to cover all the locations where the individual has contracted to provide services, which may require multiple cities and zip codes.

Rationale. Adding all of a provider's locations will strengthen the use case because consumers looking for a specific provider, particularly one they may have already been using, will want to know whether that provider is practicing in a location with which they are familiar. Since issuers may use different criteria to determine which location is primary, a search aggregator intended to show only primary location may yield the confusing result that the same doctor is practicing in one location in this QHP, another location in that QHP, and so on – which could lead consumers to question whether they are even looking at the same doctor despite the same name.

Specialty

Issue. The schema for individuals includes a field for specialty, but does not define this field.

Recommendation. Delete this field.

Rationale. To support the overriding use case, specialty is superfluous. Presumably, consumers looking for a specific provider know why they want to see that provider. Moreover, issuers do not use a common data dictionary or standard data definitions, which introduces the potential for a serious apples to oranges problem that would lead to more, not less, consumer confusion (e.g., why does the same doctor appear to have a different specialty across different QHPs?).

If CMS wishes to include specialty for future years other than 2016, it should consider using the Healthcare Provider Taxonomy Code Set, maintained by and available through the National Uniform Claim Committee. However, issuers that do not currently use this taxonomy code in their own systems

would need to crosswalk their internal specialty codes to taxonomy codes to create the machine readable file. Depending on the status of their current systems, issuers will vary widely in time and resources needed to create cross-walks to standardize their data in machine-readable files. Thus, submitting standardized taxonomy codes for 2016 is not possible given the tight timeline CMS will be providing to issuers for this project prior to open enrollment for 2016. It would be necessary for CMS to work with industry on revising and testing IT systems to use the taxonomy code set in 2017 or 2018.

Accepting Patients

Issue. The schema includes a field "Accepting Patients," defined as "Is the provider accepting patients?," true or false. Whether or not a provider is accepting [new] patients, a seemingly simply question, defies easy answer because of significant issues related to accuracy and the rate at which this answer can change, making it highly problematic to use in a search aggregator, whose results may display delayed or out-of-date information. Also, while the provider may not be accepting new patients, they may agree to keep existing patients that have joined a new health plan.

Recommendation. Delete this field from the schema.

Rationale. Lack of timely and accurate reports from providers about changes in provider directory attributes (e.g., changes in location, network participation, and accepting new patients) is a major impediment to maintaining accuracy. As URAC testified to the NAIC Network Adequacy Model Review (B) subgroup on March 29, 2014, "If providers are not forthcoming [about meeting their] co-responsibilities, plans are stuck." URAC also noted that Plans with large networks struggle to meet URAC's standard for updates within 45 days when, for example, a provider moves but does not report it for 30 days.

Some timeliness and accuracy failures may be due to providers not sending updates as failures to provide updates rarely trigger sanctions. In addition, certain types of provider directory information is highly subject to variations in reporting depending on how the respondent in the provider's practice interprets the question, the rapidity of changes in the practice's environment, or the number of payers with whom a provider contracts. For example, administrative staff is often not familiar with the terminologies used by multiple payers with multiple products, a problem exacerbated by high staff turnover. This leads to confusion and misinformation from physicians' offices about the networks or products in which the physician is participating and accepting new patients (a problem worsened in multi-physician practices where physicians vary in whether they do or do not participate).

Plans conducting audits report that answers from office staff to whether a physician is accepting patients, can vary wildly because (1) staff confuse which products have closed panels and which have open panels; (2) some staff interpret the question as referring to the day or week in which it is asked, others interpret it in the context of longer periods – answers depend greatly on precisely how the question is

asked; (3) for providers practicing in multiple locations with different policies, staff may provide a blanket response based on only one location; and (4) practices may accept some, not all, new patients (e.g., certain family members or friends of existing patients.).

Moreover, audits show that open and closed panel changes occur very frequently for some offices, because of factors such as vacations, physician turnover, and wide swings in patient volume. One Plan reports that it is not uncommon for many of its behavioral health practices in particular to respond differently to “accepting new patients” depending on whether asked in the morning or in the afternoon.

Finally, Plans report that busy office staff get frustrated by the volume of contacts about status changes from multiple payers, auditors, and secret shopper vendors: one Plan in a state that conducts independent audits reports that may practices in its region have said they will no longer provide demographic updates over the phone and asked the Plan to "send in a file and they'll review it." However, experience shows that if verification is not provided over the phone, it is rare that the Plan will ever get back the corrected file. Therefore, it is important that CMS conduct robust outreach to professional associations and trade associations representing providers to underscore the importance of their members’ cooperation in ensuring the accuracy of provider directories.

Thus, a seemingly simple question, whether a provider is accepting [new] patients, can be challenging to measure and difficult to maintain accurately. Including this field in the machine-readable file raises great risks of giving consumers misleading information that will add to, not lessen, consumer confusion.

Facility Type

Issue. The schema includes a field for facility type, but does not define this field.

Recommendation. Delete this field.

Rationale. As for individuals, facility type is superfluous to support the overriding use case. Moreover, there is no technically recognized national standard code set for facility type. One may be able to derive facility type from a taxonomy code or from the type of bill code used on an institutional claim, but in neither case is there a discreet code set at an industry level for facility type.

DRUGS - DRUGS.JSON

Issue. The PRA and developer documentation raises several issues, challenges, and concerns pertaining to the types of data elements these selected issuers may be required to submit, especially for the initial year of use.

Recommendation. Limit the data elements to support the simplest data use cases at least for the initial year of implementation to ensure data accuracy. Remove drug-name; quantity limits; drug tiers; cost-sharing sub-type.

Rationale. Drug file data elements should be limited to the minimum necessary elements to support only the basic use case, which will allow members to know what drugs are covered on a formulary. More complex cases can be added in future years. The phasing in of more complex use cases over time is consistent with the approached used for the Medicare Part D Plan Finder.

- **Remove 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. For RxCUIs, we seek clarification on source for RxCuis (i.e. formulary reference file vs RxNorm source)

- **Remove 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 online drug list.

- **Remove 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.

- **Remove Cost sharing sub-type:** The search tools should focus on enabling consumers to know what drugs are on formulary and should not make any detailed analysis around cost implications. The information on pharmacy drug pricing will be provided elsewhere as part of the plan's description, plan brochure and Summary of Benefits and Coverage. Thus we recommend the file not include information on pharmacy types and drug co-pay and co-insurance amounts.

We are also concerned that providing specific cost-sharing will create significant confusion as individuals consider plans. This is due to the expanded permutations of formularies that would have to be provided to accommodate differing cost sharing designs based on metallic status of a plan. For example, the formulary that is applicable to three different metallic plans (with the only difference being the applicable cost sharing for each tier) would result in three different formularies to accommodate the differing cost sharing.

Finally, cost-sharing information will vary for each consumer depending on how that person has progressed through the plan design over the course of the plan year. For example, cost-sharing changes when a consumer reaches the deductible and changes again when the out-of- pocket maximum is reached. Providing all of this information on a formulary would be unnecessarily cumbersome and confusing for consumers to the point where it is of little or no value to them.

- Given the more detailed information in the plan's online drug lists, we recommend that direct links to health plan websites be included. Specifically, we recommend the addition of a formulary URL that goes directory to the health plan's list of covered drugs for the specific plan or plan variation.

Issue. While some issuers may have highly tailored formularies that vary from one plan (14-digit QHP ID), many issuers have broader formularies that are consistent across multiple product lines. It is important that machine readable file maintains the flexibility for issuers to accurately reflect their formulary and drug list information in a streamlined manner.

Recommendation. We recommend that the machine readable file include a Formulary ID data element to organize drug information by formulary.

Rationale. The plans JSON file requires that for each plan (14-digit QHP ID), an issuer list all formulary information associated with that plan. This would be duplicative for issuers who have the same formulary across multiple plans or products. The 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 drug with a particular plan, instead drugs are associated with a formulary, which is then assigned to a plan or product.

Thus, in the plans JSON file, we recommend that formulary information should be organized by Formulary ID, then each health plan could be associated with that ID, rather than re-listing information for every plan that uses that formulary. Similarly, in the drugs JSON file, drug information should be sorted by formulary (which is then linked to a plan in the plans JSON file) rather than listing every plan ID that offers a 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.

This process would also allow a PBM to administer the data collection and update of the Drugs.json file as they would just use the "formulary ID" to pair the plan to the corresponding formulary. The issuer does not necessarily pass plan information to the PBM, so including a mixture of issuer and PBM information in the Drugs.json file would require the file to pass through and be processed by both entities before posting it externally, doubling the burden, complexity of the process, requiring new coordination, and increasing the risk of errors. It would also reduce the overall burden as a single PBM would develop the process for all its clients.

UPDATES

Drugs

Issue. CMS indicates that issuers should update the formulary information in a machine-readable format not less than monthly.

Recommendation. Allow plans to establish their own update schedule based on when changes are made to the formulary; do not limit a plan's ability to make updates to formulary by requiring updates first to be made to the machine readable file.

Rationale. The standard for commercial plans is for formularies to be updated at least quarterly, and we think that, at the very least, that standard should be utilized here as well. P&T committees generally meet quarterly and HHS has finalized in the Notice of Payment and Parameter Rule that such committees meet at least quarterly. We believe there are other less restrictive alternatives than updating formulary information in a machine readable file for assuring that individuals have access to as current a formulary as possible. For example, plans have 800 call center numbers where an enrollee or a prospective enrollee can call to find out the status of a drug on the formulary.

In addition, BCBSA is concerned that the approach set forth by HHS essentially would require that drugs on a formulary be frozen until the machine readable file can be updated, which would not allow plans to make prompt changes, especially as new evidence becomes available on medications which could change previous decisions on the effectiveness or safety of medications, or move drugs to a different tier as a generic drug becomes available. Issuers must be able to make formulary changes to provide the most appropriate to their members at any time.

Providers

Issue. CMS requires QHP issuers to update provider data not less frequently than monthly. However, unlike the data schema for plans.json/formulary sub-type, there is no field indicating the last time the provider directory was updated.

Recommendation. Add a data field to providers.json indicating the date on which the provider directory was last updated.

Rationale. Including date of last update will alert consumers to the variable nature of provider directory information, and give them added inducement to go to issuers' electronic provider directories for greater detail and search functionalities. Including dates would also give third-party software developers added inducement to minimize consumer confusion by caveating the results of their applications (see DUA discussion on disclaimers).

THIRD PARTY SOFTWARE DEVELOPERS

Issue. CMS's major rationale behind the machine-readable requirement is to increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand plans' formulary drug lists and the availability of providers in a specific plan. Even if the machine-readable files are modified to support the two overriding use cases, giving

software developers access to this information outside the context of any data use agreement(s) (DUA) raises a host of thorny issues around responsibilities for data accuracy and potential liabilities.

Recommendation. CMS should develop a master data use agreement (DUA) that any third party software developer wishing to access the JSON files would have to sign.

The DUA should be for a one-year contract period and:

- Require that vendors apply for and receive security keys to access JSON files. CMS should provide a registry of all security keys assigned, and issuers should be able to track when a security key is being used and who is using it.

- Specify guidelines for accessing JSON files to avoid exorbitant expenditures on hardware and bandwidth that issuers might otherwise have to make. For example, vendors may have to request and comply with schedules and maintenance downtimes from issuers.

- Require that vendors hold issuers harmless against liability, cost, or expenses which may be sustained as a result of vendor errors in provider directory or formulary information or inaccuracies in the data pulled from the JSON files by maintaining errors and omissions insurance in an amount with a specified monetary minimum per claim in force during the contract period.

- Require that vendors show that they have no actual or perceived conflict of interest in ownership or investors that could impinge on an issuer's competitive position; and prohibit vendors from displaying or manipulating data in a way that could give any issuer(s) a competitive advantage over other issuers.

- Require standard disclaimer language (see "Disclaimer" discussion below).

Rationale. CMS has an interest in minimizing administrative burden on issuers (to promote affordability), in ensuring high-quality applications that do not confuse or mislead consumers, and in protecting issuers from unacceptable legal or business risks.

DISCLAIMERS

Providers

Issue. Any search aggregation tool, whether a new search field on the healthcare.gov learning window or a third-party developer's app, is dependent on data under the control of QHP issuers.

Recommendation. CMS should develop standard disclaimer language to use on the new search field, and to be used by any third party vendor, clarifying that issuers' own provider directories enable searches that go beyond the initial uses cases, may be more up-to-date, and provide needed context about benefit design (e.g., referral requirements for specialists, or different cost-sharing associated with different tiers of providers) – consumers should always go to the issuer's website. In addition, the disclaimer should state:

- Even though issuers make every effort to ensure the accuracy of the information, they cannot be responsible for every omission and error and, therefore, it is important always to contact the provider directly to confirm any information – including whether the provider is accepting new patients at the particular time or location that is needed – or the plan to confirm details about coverage.

- Information is based on plans' reasonable efforts to provide accurate and up-to-date data as of the date specified.

- Consumers should always follow health plan rules regarding prior-authorization and other requirements prior to 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 a drug listed on the tool.

- Health plans' website provider directory tools may include information that is updated more frequently.

Rationale. Such a disclaimer is necessary to set rational consumer expectations and to promote greater engagement by consumers in their choice of QHPs. A disclaimer provides details on 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. It protects issuers by making consumers aware that data obtained through such apps is not under the control of issuers, and issuers are not responsible or in any way liable for the content of such data, including without limitation its accuracy, or any other aspect of their content (consistent with the DUA). Nothing would prevent an issuer from continuing to post its own disclaimers.

<u>Drugs</u>

Issue. Issuers should be protected against consequences of inaccuracies caused by third parties in the process of aggregating and "cleansing" data.

Recommendation. CMS should develop standard disclaimer language that CMS will use on the new search field and that any third party vendor must use to clarify:

- The importance of consumers talking to their doctor about prescribing formulary medications, which may help reduce out-of-pocket costs. A plan's formulary should be used to help consumers and their doctors in selecting an appropriate medication.

- The need for consumers 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 information is based on plans' reasonable efforts to provide accurate and up-to-date data 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.
- Health plans' website formulary tools may include information that is updated more frequently.

Rationale. Same as for the provider disclaimer.

BURDEN

Issue. The PRA notice estimates that it will take each QHP issuer only 5 employees working a total of 96 hours – for a total burden cost of about $5,200 – to provide and update the JSON files. Based on preliminary estimates, this burden seems grossly understated. One Blue Plan with QHPs in more than one Insurance Marketplace estimates it would take 8 to weeks to extract, translate, and upload the files initially, not to mention time for testing (which is difficult to determine at this point because the systems architecture and interface for the new CMS search field/capability is not known). Another Blue Plan with QHPs in one state has estimated that it would take more than five times the number of hours in the CMS estimate simply to ready the JSON files for interfacing with CMS, and perhaps 800 more hours to integrate, test, and implement the files and program interfaces.

Recommendation. CMS should work with industry on developing more realistic estimates of the burden.

Rationale. The estimate of burden does not reflect the breadth of resources and processes needed to collect and produce the files as envisioned. The workload to build the base for the file production in this format as well as the needed processes to ensure accuracy of the data prior to post is greater than that captured in the PRA. This is largely due to plan information data source, provider information data source, and pharmacy information data source coming from different systems. In the tech specs for the JSON files it appears to indicate that at the very least plan data and formulary data will need to be

combined for the final files. We do not believe that this workload is accurately reflected in the preliminary estimate.

Nor does the estimate reflect the costs of hosting the files, which could be significant depending on the number of third parties and the frequency with which they pull data from issuers' files.

Finally, the required fields for the formulary file include fields that are not in the SERFF submission drug list (QL's). Thus it appears that issuers cannot simply take their drug template document and convert that to this format – but instead would need to create additional processes to create the document to be posted on the website. This will require additional resources not accounted for in the estimated burden review.