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VIA ELECTRONIC FILING – http://www.regulations.gov

The Honorable Sylvia Matthews Burwell  
Secretary, Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Jacob J. Lew  
Secretary, Department of the Treasury  
1500 Pennsylvania Avenue, NW  
Washington, D.C. 20220

The Honorable Thomas E. Perez  
Secretary, Department of Labor  
200 Constitution Avenue, NW  
Washington, DC 20210

Re: CMS–9938–P; Comments regarding the Proposed Rule on the Summary of Benefits and Coverage and the Uniform Glossary

Dear Mr. and Mmes. Secretary:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the proposed rule on the Summary of Benefits and Coverage and the Uniform Glossary (CMS–9938–P) as provided for under the Affordable Care Act (ACA). PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $550 billion in the search for new treatments and cures, including an estimated $51.1 billion in 2013 alone.

The proposed rule updates the 2012 final rule implementing section 2715 of the Public Health Service Act, which was enacted as part of the ACA. Section 2715 directs the Department of the Treasury, the Department of Labor and the Department of Health and Human Services (the Departments) to “develop standards for use by a group health plan and a health insurance issuer . . . in compiling and providing to enrollees a summary of benefits and coverage [SBC] explanation that accurately describes the benefits and coverage under the applicable plan or coverage.” Since the 2012 rule was issued, the Departments have released a stream of interim guidance to clarify the regulations, and the 2014 proposed rule aims to codify much of this
guidance and update the 2012 rule to account for changes made to the insurance markets since 2012.

PhRMA supports efforts to promote consumer access to clear and complete information about plan benefits and coverage. Easy access to information of this kind is necessary in order for beneficiaries to make informed decisions about their health care coverage. To improve the SBCs and provide clearer and more accurate information to consumers, we suggest changes to the SBC and the accompanying documents related to the following areas:

- Direct formulary links
- Clearer information about plan deductibles
- Clearer information about coverage of contraceptives
- Coverage examples
- Definitions of specialty drug, preventive services, in-network provider, copayment and coinsurance

We explain each of these matters below.

More Information about Prescription Coverage

Direct Link to the Plan Formulary

Coverage of prescription medicines is a critical factor that many beneficiaries take into consideration when choosing a health plan. The proposed rule requires SBCs to include uniform definitions of insurance and medical terms and a brief description of coverage, including coverage examples and benefit scenarios. Because prescription medicines are an integral component of treatment and pharmacy benefits often have different cost sharing limits and requirements than other health benefits, we urge the Departments to ensure that SBCs provide the essential information about prescription drug coverage that consumers need to select and use a health plan. While we recognize that it is not practical to provide all relevant information in an SBC, the rule should require that plans provide easily accessible internet links where more detailed information can be found. The proposed instructions’ requirement that the SBC contain an internet link where an individual can “find more information about prescription drug coverage” is insufficient to ensure that consumers have the information they need, and could leave consumers on their own to navigate complex websites in order to find complete formulary information.

Recognizing that navigating plan websites can be difficult, and noting that consumers should not have to log on and enter a policy number or otherwise navigate an issuer’s website before locating the formulary, the Centers for Medicare & Medicaid Services (CMS) clarified in the “Final 2015 Letter to Issuers”¹ that issuers must submit direct formulary links to be posted on Healthcare.gov. Given that CMS has acknowledged the importance of including direct formulary links on Healthcare.gov, by the same rationale, the Departments should require on

page 11 of the proposed instructions that the link on page 2 of the sample SBC template link directly to the formulary for the given health plan. This formulary should meet the requirements laid out in the 2016 Notice of Benefits and Payment Parameters.

We believe that direct access to a complete plan formulary is crucial to empowering patients to better understand their coverage options. Clear instructions to plans are important to assure that formulary documents are available directly from the SBC, are complete, and are in a format that promotes easy comparisons across plans.

**Clarification around the Deductible**

SBCs are meant to be simple resources that are easy to read and understand, and to provide assistance to consumers in choosing a health plan. These documents are supposed to be easy to follow, yet they often do not present clear information about one important factor in plan selection—the plan’s deductible(s). For example, SBC documents lack uniformity and clarity around what services are subject to a deductible. The proposed rule seeks to finalize an almost identical set of instructions to those finalized in the 2012 iteration of the rule. It appears that the SBC instructions or SBC forms themselves provide insufficient detail to issuers, leading to SBCs that have information about plan deductibles that is inconsistent with other plan documents and may be unclear to consumers. We have attached as Appendix A some annotated examples of SBCs released by plans under the current instructions that do not present information about the deductible that matches other plan documents. Given these examples, we are concerned that the current and proposed SBC requirements are not adequate to ensure that SBCs always help consumers easily understand whether and how different kinds of medical care count towards the deductible. We suggest that the Departments work with issuers and consumer groups to make the instructions and SBC template clearer.

For example, in our analysis of SBCs and other plans documents, we have encountered five approaches to how medicines count toward deductibles: combined deductible, separate medical and drug deductibles, medical deductible with first-dollar coverage for medicines, deductibles that only apply to certain formulary tiers and nested deductibles. Plans with nested deductibles have separate medical and drug deductibles, but spending towards the smaller deductible also counts to the larger deductible. For example, if a plan has nested deductibles and a $1,000 medical deductible and a $500 drug deductible, a person who has spent $400 out-of-pocket on medicines would need to spend an additional $600 on medical care to meet the medical deductible. The various deductibles outlined above show that there is a great deal of variety in the types of deductibles a plan could have and a lack of standardization in identifying these deductibles on the SBCs. This raises concerns because deductibles have such a significant impact on potential out-of-pocket costs.

There are two areas of the SBC where the Departments should consider making the instructions more clear so that issuers complete SBCs in a way that provides clear and adequate details about how deductibles apply to medicines and other services: the Important Questions and Answers sections on deductibles on page 1 and the Common Medical Event sections on pages 2-3.
Important Questions and Answers section:

The 2012 final and 2014 proposed instructions clearly state on pages 3 and 5 respectively that, “If there is an overall deductible, underneath the dollar amount, plans and issuers must include language specifying major categories of covered services that are NOT subject to this deductible. For example, ‘Does not apply to preventive care and generic drugs.’” However, it appears that not all plans are clearly identifying when medicines and possibly other services are exempt from the deductible. The Departments should work with issuers and consumer groups to ensure that consumers receive the required accurate and clear information about which types of care are not subject to a deductible.

Common Medical Event Fields:

Rather than require consumers to flip or scroll through multiple pages of an SBC to recall how the deductible applies to medical services and prescription drugs, the Common Medical Event fields should inform the potential enrollee of whether a deductible applies to each specific service. Therefore, in order to ensure that enrollees can clearly understand which of their medical services are subject to a deductible, we suggest that the Departments consider adding an additional column to pages 2-3 of the proposed template where a checkmark can be placed next to each service that is subject to a deductible.

Working with issuers to clarify the instructions and adding clear information to the SBC undoubtedly will minimize confusion and allow consumers to understand the actual cost-sharing requirements of health plans, both prior to enrollment and once enrolled. SBCs are designed to offer a clear, uniform, understandable document for consumers to have accurate information about health plans. Offering clarity on the complexities of deductibles would bring the system much closer to that goal.

Clarification on Coverage of Contraceptives

There appears to be a lack of transparency related to the coverage of contraceptives in some plans. In these plans, there is no indication on the SBC that contraceptives are part of the list of preventive services that are covered without cost sharing, nor is there any indication on the formulary that any contraceptives are covered without cost sharing. While the formulary may include a list of contraceptives that are covered and the tier on which they are covered, there is no indication that some of these products may be available without cost sharing. This practice is not ubiquitous, and there are some plans that are providing details in the SBC on their coverage of contraceptives. The plans providing this information are often doing so in the coverage and limitations section for prescription drug coverage (See Appendix B). We suggest that the Departments work with insurers and consumer groups to designate a place on the SBC to specify that many contraceptives are available without cost sharing as a preventive service and also include a link to plan formulary, which would identify the specific products available at no cost sharing.

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Coverage Examples

Replace Fracture of a Foot Coverage Example

In the proposed regulation, the Departments have suggested adding a third coverage example—the cost of treatment for a simple foot fracture. While this scenario has broad applicability, enrollees would be better served by comparing costs for a chronic condition that could potentially result in higher out-of-pocket costs if not adequately covered. The vast majority of health care spending is concentrated among individuals with chronic conditions, and therefore, we would suggest the Departments consider replacing the foot fracture example with either the cost of a heart attack or treatment of asthma for one year. Both examples are either a chronic condition or the byproduct of one, and would illustrate the value of health insurance by showing consumers a coverage example with high total costs. Additionally, the Kaiser Family Foundation estimates that by 2019, 12 percent of exchange enrollees will have hypertension, 3 percent will have a heart condition and 5 percent will have a chronic pulmonary condition. These are some of the highest prevalence conditions in Kaiser’s analysis and show the proportion of enrollees that could be assisted by choosing either a heart attack or asthma for the third coverage example. The departments could also consider replacing the simple foot fracture example with another chronic condition, such as breast cancer. We understand that breast cancer was recommended for inclusion by an NAIC working group prior to the 2011 proposed rule. We urge the Departments to revisit this suggestion and add a chronic condition as the third coverage example.

Concerns with Methodology used to Estimate Costs

In addition to the new coverage example chosen, we have concerns about the methodology used to estimate the costs and the comprehensiveness of information presented in the coverage examples. For instance, the assumptions built into the calculator result in severely underestimated costs for prescription drugs. The assumptions apply the cost-sharing rules for generic drugs to all prescription drugs used in the treatment, even if there is no generic equivalent for a particular medicine. This is particularly problematic for a condition like well-controlled diabetes where prescription drugs may be the most expensive component of treatment and do not usually have a generic equivalent. In the diabetes coverage example, prescription medicines are the most expensive component of care ($3,300 of $6,100 total). Most drug costs are likely for insulin, which does not have a generic equivalent. Because most health plans have tiered drug formularies which have higher cost-sharing for non-generic drugs, the calculator is severely underestimating the true cost faced by an individual getting treated for diabetes, and therefore is providing misleading information to potential enrollees.

Finally, the coverage example only shows costs for individuals and not for a family. Many people are buying coverage not just for themselves but for their spouses and children as well. Deductibles and out-of-pocket caps are different for family plans and as currently written, none of the proposed examples make clear what out-of-pocket costs a family would pay. At a minimum, the example should include language clarifying that cost sharing may be different under a family plan.

The coverage examples are one of the most popular tools in the ACA\(^6\) which makes these issues with the calculator particularly concerning. When the initial FAQ was issued for the coverage example in 2012,\(^7\) the Departments explained that the calculator was only meant to be a one year “transitional tool” for plans to use until the requirement began for health plans to fill out the coverage example template by processing the full list of claims associated with each coverage example through the plan’s or issuer’s system. The Departments acknowledged in the proposed rule that the calculator was supposed to be temporary because using the calculator’s limited number of inputs would provide a less accurate result than if an issuer obtained the out-of-pocket estimate by processing the full list of claims within its own system.\(^8\) Despite acknowledging the inaccuracies and limitations of the calculator, The Departments have proposed to extend the use of the calculator until “superseded by further guidance.”\(^9\) Given the methodological problems stated above, and the popularity and potential utility of these coverage examples, we urge the Departments to revisit the proposal to keep using the calculator and return to the initial plan of transitioning to accurate cost-sharing amounts based on each plan’s actual cost-sharing parameters for the particular claims in each example.

**Uniform Glossary**

The rule proposes revisions to the uniform glossary including changing some existing definitions and adding several new definitions to help individuals better understand and compare offered coverage.

*Specialty Drug*

We appreciate that the Departments are trying to make shopping for insurance coverage even more clear for the millions of potential enrollees; however, we urge the Departments to be careful in how they define “Specialty Drug” so as to avoid misinforming or confusing enrollees. For example, the phrase “difficult to dispense” is unclear and may confuse or mislead consumers. We also suggest replacing the definition of “Specialty Drug” in the glossary (and changing its accompanying reference in the proposed instructions and sample SBC template).

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with “Specialty Category” and making some small adjustments to the wording suggested in the draft glossary. The revised wording we suggest is:

Specialty Category: A formulary category, or “tier,” sometimes used to separately group prescription drugs that, in general, require special handling or ongoing monitoring and assessment by a health care professional. If the plan’s formulary uses categories, and certain drugs are placed in a specialty category, you will likely pay more out of pocket for drugs in that category.

Preventive Care

Healthcare.gov lists the set of preventive services\(^\text{10}\) that most health plans must cover without cost-sharing. Most services on that list were included in the proposed definition, but vaccines and contraception were omitted from the draft definition. We suggest adding vaccines and contraception to the definition to improve accuracy. We suggest the following addition, highlighted in bold, to the definition of preventive care in the draft glossary:

Preventive Care: Routine health care, including screenings, check-ups, **vaccines, most contraceptives**, and patient counseling, to prevent or discover illness, disease, or other health problems.

Preferred Provider

The Departments use the term "preferred providers" synonymously with "in-network providers." In light of the proliferation of tiered networks, the Departments should revisit their definitions related to provider networks and determine if additional information should be added in order to provide clarification for consumers. We suggest changing the definition from "Preferred Provider" to "In-Network Provider," outlined below, and making a global change to all corresponding references throughout the document. The revised wording we suggest is:

In-Network Provider: A provider who has a contract with your health insurer or plan to provide services to you at a discount. Check your health insurance policy or plan document to see if you can see all in-network providers without paying extra or if your health insurance or plan has a “tiered” network and you must pay extra to see some providers. In a “tiered network,” your health insurance or plan may have preferred and non-preferred providers, all of whom are “in-network” providers. However, you may have to pay more for seeing a non-preferred provider as compared to a preferred provider.

Coinsurance

The current definition of coinsurance could be misunderstood by consumers to mean that coinsurance applies before an enrollee has reached the deductible. We suggest changing “plus” to “after” in the definition of coinsurance in the draft glossary in order to make sure it is clear

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\(^{10}\) [https://www.healthcare.gov/preventive-care-benefits/](https://www.healthcare.gov/preventive-care-benefits/)
that coinsurance only applies once you have met your deductible. The revised wording we suggest is:

Coinsurance: Your share of the costs of a covered health care service, calculated as a percentage (for example, 20%) of the allowed amount for the service. You generally pay coinsurance after any deductibles you owe. (For example, if the health insurance or plan’s allowed amount for an office visit is $100 and you’ve met your deductible, your coinsurance payment of 20% would be $20. The health insurance or plan pays the rest of the allowed amount.)

Copayment

Similar to the issue with coinsurance above, it is possible that a consumer may assume that he is only responsible for a copayment and not realize that he may also be required to reach a deductible. We suggest adding the bolded sentence to the definition of copayment in the draft glossary. The revised wording we suggest is:

Copayment: A fixed amount (for example, $15) you pay for a covered health care service, usually when you receive the service. You generally pay a copayment after any deductibles that you owe. The amount can vary by the type of covered health care service.

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We appreciate your consideration of our comments. Please feel free to contact us with any questions.

Sincerely,

/s/  
__________________________________  /s/  
Lisa Joldersma  Maya Bermingham  
Vice President, Policy and Research  Vice President and Senior Counsel

/s/  
__________________________________  
Rebecca Davison  
Senior Manager, Policy and Research
Appendix A

Deductible Example 1:

As seen above, the overall deductible for the Blue Cross Blue Shield of Louisiana: $2000, a Multi-State Plan is $2,000. The 2012 final and 2014 proposed instructions clearly state on pages 3 and 5 respectively that, “If there is an overall deductible, underneath the dollar amount, issuers must include language specifying major categories of covered services that are NOT subject to this deductible. For example, ‘Does not apply to preventive care and generic drugs.’” According to Healthcare.gov, “All Marketplace plans and many other plans must cover the following list of preventive services without charging you a copayment or coinsurance. This is true even if you haven’t met your yearly deductible.” Despite the instructions, the plan above has not explicitly stated in the “Overall Deductible” row that preventive services are not subject to a deductible. This omission means that it is possible that other services, such as prescription drugs, are similarly not subject to a deductible, but that is unclear from how this document has been written.
Additionally, giving further evidence to the lack of clarity about which services in the plan are subject to a deductible, as can be seen in the excised page below from the plan brochure, the plan clearly states that if a service has a copayment as its cost-sharing structure, the service is not subject to a deductible.
However, as can be seen in the excised page from the plan’s SBC, while Tier 1-Tier 3 prescription medicines use copayments, nowhere in either the deductibles section on page 1 (above) or the Common Medical Events section on page 3 does the plan make clear that these prescription drugs are not subject to a deductible. These examples demonstrate that the current level of detail in the SBC proposed instructions provide insufficient guidance for issuers to adequately communicate the amount of and which services the plan’s deductible applies to.
**Deductible Example 2:**

In the Molina Michigan Silver 250 plan, the specific services deductibles section on page 1 shows that there is a separate deductible for prescription drugs and lists the amount ($200). The Common Medical Events section on page 2 outlines the various cost-sharing amounts that correspond to the given prescription drug tier. Given this information, a consumer would likely assume that all of his prescription drug costs would be subject to the $200 deductible.
However, as can be seen in the excised page from the plan brochure below, that is not the case. The plan brochure clearly states that only non-preferred and specialty drugs are subject to the prescription drug deductible. This means that consumers who could benefit from choosing this plan because they primarily take medications on one of those tiers might be dissuaded from selecting it if they believe that all their prescription medications would be subject to the $200 deductible. This inconsistent information between the SBC and the corresponding plan brochure is yet another example of the need to further clarify the instructions surrounding how deductibles are listed and explained on an SBC.
Appendix B

Contraceptives Example

As can be seen in the SBC below, the Blue Cross Blue Shield Kansas State Employee Health Plan C lays out in the Limitations & Exceptions column of the prescription medications section that there are some contraceptives that are available with no cost-sharing.

<table>
<thead>
<tr>
<th>Common Medical Event</th>
<th>Services You May Need</th>
<th>Your Cost If You Use a Network Provider</th>
<th>Your Cost If You Use a Non Network Provider (plus any remainder)</th>
<th>Limitations &amp; Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you need drugs to treat your illness or condition</td>
<td>Generic drugs</td>
<td>100% until deductible is met followed by 0% coinsurance (retail and mail order) per 31 day supply.</td>
<td>100% until deductible is met followed by 0% coinsurance (retail and mail order) per 31 day supply.</td>
<td>First fill is a 31 day supply at retail and mail. A 93 day supply is allowed at retail and mail for subsequent fills. Deductible: $3,600 / Ind $5,200 / Family Over-of-Pocket Maximum $2,600 / Ind $5,200 / Family Contraceptives: Covered with 0% coinsurance. Non-Preferred Contraceptives: Covered subject to member Deductible.</td>
</tr>
<tr>
<td></td>
<td>Non-Prescribed drugs</td>
<td>Same as Generic</td>
<td>Same as Generic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Specialty drugs</td>
<td>Same as Generic</td>
<td>Same as Generic</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>If you have outpatient surgery</td>
<td>Facility fee (e.g., ambulatory surgery center)</td>
<td>Deductible plus 0% coinsurance</td>
<td>Deductible plus 20% coinsurance</td>
<td>Prior Authorization is required.</td>
</tr>
<tr>
<td></td>
<td>Physicians/nurse fees</td>
<td>Deductible plus 0% coinsurance</td>
<td>Deductible plus 20% coinsurance</td>
<td></td>
</tr>
<tr>
<td>If you need immediate medical attention</td>
<td>Emergency room services</td>
<td>Deductible plus 0% coinsurance</td>
<td>Deductible plus 0% coinsurance</td>
<td>Must meet emergency criteria. Copay waived if admitted within 24 hours.</td>
</tr>
<tr>
<td></td>
<td>Emergency medical transportation</td>
<td>Deductible plus 0% coinsurance</td>
<td>Deductible plus 20% coinsurance</td>
<td>Must meet emergency criteria.</td>
</tr>
<tr>
<td></td>
<td>Urgent care</td>
<td>Deductible plus 0% coinsurance</td>
<td>Deductible plus 20% coinsurance</td>
<td></td>
</tr>
<tr>
<td>If you have a hospital stay</td>
<td>Facility fee (e.g., hospital room)</td>
<td>Deductible plus 0% coinsurance</td>
<td>Deductible plus 20% coinsurance</td>
<td>Prior authorization is required.</td>
</tr>
<tr>
<td></td>
<td>Physicians/nurse fees</td>
<td>Deductible plus 0% coinsurance</td>
<td>Deductible plus 20% coinsurance</td>
<td></td>
</tr>
</tbody>
</table>

Questions: Call 1-800-333-0397 or visit us at www.bcbsks.com. If you aren’t clear about any of the bolded terms used in this form, see the Glossary. You can view the Glossary at www.cms.gov or call 1-855-336-2388 to request a copy.
In comparison, the example below from a Health Partners Minnesota $2,500 Plus Silver plan shows what the majority of plans are leaving out of their prescription medications sections: clear language stating that many contraceptives are covered with no cost sharing.