



PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

Mark Merritt
President & CEO

October 21, 2011

Dr. Donald Berwick, Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS—9982—P
P.O. Box 8016
Baltimore, MD 21244-1850

Dear Dr. Berwick:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the Notice of Proposed Rulemaking titled “Summary of Benefits and Coverage and the Uniform Glossary” and the “Summary of Benefits and Coverage and Uniform Glossary—Templates, Instructions, and Related Materials Under the Public Health Service Act”, published in the Federal Register on August 22, 2011. PCMA is the national association representing America’s pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, and Medicare.

PCMA commends the Departments for allowing prescription drug formulary information to be available on a website and believes this approach should be used more extensively for the SBC in general.

In addition, PCMA supports the goal of ensuring that enrollees are fully-informed when they select the health plan best suited to their individual and family needs. We believe this goal can and must be achieved in a manner that promotes efficiency, takes full advantage of existing electronic technology, and encourages innovation.

The NPRM and the companion Solicitation of Comments propose standards for implementing Section 2715 of the Public Health Service Act (“PHSA”), as adopted by the Affordable Care Act (“ACA”). PHSA Section 2715 directs the Secretary to develop a summary of benefits and coverage (“SBC”) explanation to assist individuals with understanding their health insurance coverage not later than 12 months after the date of enactment of the ACA, i.e. March 23, 2011. Delay in issuing the NPRM, and ultimately the Final Rule (approximately nine months behind schedule), leaves plans and issuers with an inadequate timeframe in which to implement required changes by the March 23, 2011 SBC implementation date and presents great difficulties for compliance.

Section 2715 requires the SBC to be in a uniform format not exceeding 4 pages in length and it must include specific provisions to assist health insurance purchasers with their decisions. Section 2715 requires the Secretary to consult with the National Association of Insurance Commissioners (“NAIC”) to develop SBC standards. The NPRM adopted

the NAIC recommendations in their entirety. Representatives from our member companies and their health plan clients fully participated in the NAIC working group, and they urged the NAIC to recommend SBC standards that would work off existing disclosure rules, allow for greater flexibility, and would be less costly. These requests were not accepted.

PCMA believes the SBC, as proposed, duplicates efforts because the Form provides information that is already supplied by health plans. In addition, the proposed Uniform Glossary contains provisions and terminology that may be misleading or confusing for many consumers due to conflicting interpretations of the listed terms. Further, implementation costs for health plans, insurers, and employers will be significant and will increase the costs of health insurance coverage in all markets.

PCMA Concerns with the NPRM

The SBC requirements proposed in the NPRM pose substantial challenges for health plans and insurers. PCMA's specific concerns are set forth below:

- The March 23, 2012 timeframe is unreasonable because the Departments were late in issuing the NPRM and the Form will require industry-wide changes to internal information technology systems and similarly sweeping changes to enrollment and renewal processes.
- The Form requirements are very expensive because there are thousands of health insurance options and policies in the market, each of which would require a customized SBC Form, and the Form is administratively difficult to prepare.
- The timelines within which Forms must be delivered to shoppers, applicants, enrollees, special enrollees, and policyholders are arbitrary and unreasonable, and do not align with plan years.
- The Form duplicates disclosure documents already provided by health plans and insurers, particularly in the large group and self-insured plan markets.
- It is unclear what constitutes a "material modification", which would trigger the 60 day advance notice rule, under the "Notice of Modifications" requirement. Would a change of a drug from one class to another, or the introduction of a generic for a previously brand only drug, trigger the advance notice requirement? Are retroactive changes to correct clerical errors during the sales or implementation period exempt from the 60 day advance notice requirement? Does the advance notice requirement apply to new state-mandated benefits?
- Although the Form allows insurers to use electronic means, the electronic delivery requirements for individuals are too limited and should be amended to allow greater flexibility. Comparison of plan benefits and enrollment is typically conducted online

for most health plans, and the proposed SBC requirements should be aligned with current electronic decision support tools.

- It is not clear whether state laws requiring similar disclosures are preempted by or are still operative in addition to the proposed SBC requirements.

PCMA Recommendations on the NPRM:

PCMA Recommendation on SBC Implementation: *The final rule should allow adequate time for implementation. We recommend that the Departments require health insurance issuers to offer an SBC no later than 12 months after the effective date of the Final Rule and at the beginning of the next plan year. We also recommend that the Departments adopt a policy of non-enforcement for 18 months after implementation of the SBC requirement. Preparation of the SBCs will entail time-consuming coordination among many vendors with which health plans contract for administration of plan benefits—including PBMs—and the additional lead time, and grace period for implementation, will assure a better product for plan participants and insurance purchasers. Further, PCMA recommends that the Departments exempt large group health plans, including self insured health plans, from the SBC requirements. Large group plans are typically customized and provide many tools to assist purchasers, via comprehensive enrollment and renewal materials as well as human resources personnel to answer questions and otherwise inform the selection process.*

PCMA Recommendations regarding Form Language:

- ***Deductibles, Out of Pocket Limit*** – *We recommend that the instructions allow a drop down menu for all the variations in the marketplace for deductibles and out of pocket limits.*
- ***Does the Plan use a Network of Providers-*** *We recommend that the instructions allow a drop down menu to show differences in network configurations.*
- ***Common Medical Event***—*We recommend that HHS remove "chemotherapy" as an example of a specialty drug*

PCMA Recommendation on Notice of Modifications: *The Departments should provide clarification on what constitutes a “material modification” and triggers the 60 day advance notice requirement. We suggest the use of examples to provide clearer guidance for issuers and group health plans, particularly regarding which types of plan changes are subject to or exempt from the 60 day advance notice requirement.*

PCMA Recommendation on Electronic Format: *We recommend that the Departments facilitate electronic delivery by easing the requirements governing how an issuer or group health plan can provide SBCs in electronic formats. The NPRM allows issuers to provide SBCs electronically to group health plans if (1) it is in a format readily accessible by a plan/sponsor; (2) the issuer would provide a paper form free of charge*

upon request; and (3) if the electronic form is an internet posting, the issuer timely advises the plan either through hard copy or through email that the SBC is available on the internet and states the specific website. The Departments should apply these standards for issuers and group health plans providing SBCs to enrollees and for issuers providing SBCs to individual policyholders. To the maximum extent possible, the Departments should allow and encourage the transmission of SBCs and related information through electronic means and avoid duplicative dissemination via paper formats.

PCMA Recommendation on State Law Pre-emption: *HHS should issue clarification on preemption issues; otherwise state regulators are likely to continue to require their own documents even if they are duplicative and contribute to consumer confusion.*

PCMA Concerns with the Uniform Glossary:

We commend HHS for issuing the Glossary simultaneously with the NPRM, in the Solicitation of Comments. While a glossary of terms could help applicants, enrollees and policyholders to better understand the terms of their coverage, the proposed Glossary may confuse them if its definitions contradict similar terms used in a plan document. If issuers and group health plans can satisfy the Glossary requirement by posting it on their websites, or providing a link to the Department’s web page, the Glossary would be much easier to implement after the Final Rule is issued.

We have concerns with some of the definitions included in the glossary, including:

- The definition of “grievance” as “A complaint that you communicate to your health insurer or plan” is not appropriate for self-insured employer –sponsored health plans. Insured plans are required by law and regulation to provide a mechanism for handling grievances or complaints raised by subscribers, but the Department of Labor does not require self-insured plans subject to ERISA to provide a similar channel for grievances. The proposed Glossary definition applies to both fully insured and self-insured plans, and is inaccurate and potentially misleading for readers.
- The definition of “preauthorization” in the Uniform Glossary implies that the decision is based entirely on “medical necessity” and this is not accurate: preauthorization in the context of prescription drug benefits is typically based on a plan’s coverage criteria which include consideration of off-label or experimental uses, potential for abuse or overuse, recommended duration of therapy, and availability of less costly front-line therapies, in addition to medical necessity.
- It is unclear under the SBC content section (p. 52446, Federal Register, Vol.. 76, No. 162) whether the Uniform Glossary definition for “prescription drug ,” defined as “drugs and medications that by law require a prescription”, applies to the requirement that plans and issuers which maintain a formulary must provide an internet address where individuals may find information about the prescription drugs covered under

the plan. We seek clarification that the prescription drug coverage information that must be provided on the formulary website does not include OTC drugs.

PCMA Recommendation: *We recommend that the Departments clarify that issuers and group health plans may post the Glossary on their websites, or mail copies of the Glossary to enrollees and policyholders upon request, but are not legally obligated to do so because the Glossary is a government document readily available on the HHS website. The Departments should add a disclaimer to the Glossary to explain that the Glossary definitions apply to health insurance in general, but may not be applicable to specific terms in a particular policy. Some policies might not allow or have balance billing features or may define out-of-pocket differently than the Glossary.*

We urge the Departments to approve the following language for use by issuers and group health plans

"This Glossary has been developed according to the requirements under Section 2715 of the Public Health Service Act. While it is intended to be educational, the terms and definitions in this Glossary may not be the same as the terms and definitions within your health plan or policy. Please consult your [issuer/plan administrator] if you have specific questions regarding the terms and definitions in your policy".

PCMA Recommendation on Definition of Grievance: *PCMA recommends clarification that the definition of grievance does not apply to self-insured plans under ERISA.*

PCMA Recommendation on Definition of Preauthorization: *PCMA recommends that the Departments clarify that preauthorization is based on more than a determination of medical necessity.*

PCMA Recommendation on Definition of Prescription Drug: *PCMA requests clarification that the definition of prescription drug, for purposes of the SBC Form, the formulary disclosure, and the Uniform Glossary definition, does not include over-the-counter ("OTC") drug products. We suggest that the Glossary definition be modified to read "Drugs and medications that by law require a prescription **written by a licensed prescriber.**"*

PCMA Recommendation on Definition of Prescription Drug Coverage: *PCMA recommends that the definition of prescription drug coverage be modified to read "Health insurance or plan that helps pay for **covered** prescription drugs and medications."*

PCMA Recommendation on Definition of Medically Necessary: *We strongly believe the proposed definition of "medically necessary" in the Glossary (p. 52529, Federal Register, Vol. 76, No. 162, August 22, 2011) is outdated and inadequate. We recommend that the Departments modify the proposed definition of medically necessary by substituting the Stanford definition for medical necessity which incorporates the following criteria:*

- *Is the most appropriate supply or level of service, considering benefits and harms to the patient;*
- *Is known to be effective in improving health outcomes;*
- *Is based on scientific evidence, to the greatest extent possible; or,*
- *If no scientific evidence is available, should be based on professional standards of care or expert opinion.*

Thank you for the opportunity to provide feedback on these very important aspects of implementing the Affordable Care Act. As always, we appreciate your consideration of our comments and look forward to continuing to work with the Departments to ensure the successful operation of the ACA.

Sincerely,

A handwritten signature in black ink, appearing to read "Kristin A. Bass". The signature is fluid and cursive, with the first name being the most prominent.

Kristin A. Bass
Senior Vice President, Policy