

October 21, 2011

Dr. Donald Berwick MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9982-P; CMS-9982-NC

Dear Administrator Berwick,

On behalf of the nearly 26 million Americans with diabetes and the 79 million more with prediabetes, the American Diabetes Association (Association) appreciates the opportunity to submit comments on the Notice of Proposed Rulemaking: Summary of Benefits and Coverage and Uniform Glossary (CMS-9982-P)(CMS-9982-NC).

The Centers for Disease Control and Prevention (CDC) estimates that as many as 1 in 3 Americans will have diabetes by 2050, and nearly one in two racial/ethnic minority children born in 2000 will develop diabetes in their lifetime, if current trends continue. The costs associated with diabetes, including diagnosed and undiagnosed diabetes, prediabetes, and gestational diabetes, and their complications, accounted for \$218 billion in direct and indirect costs in 2007 alone. Much of the economic burden of diabetes is related to its complications, such as blindness, amputation, kidney failure, heart attack, and stroke. Yet, we have made major strides in effectively managing diabetes and reducing the risk for these devastating – and costly – complications through advances in medical care, medications and other tools, patient self-management, education, and support. Access to affordable, adequate coverage that enables health care access is critically important for people with, and at risk for, diabetes. When people are not able to afford the tools and care necessary to manage their diabetes, they scale back or forego the care they need, which often leads to disabling and costly complications and suffering that could have been prevented.

The Summary of Benefits and Coverage (SBC), including the Coverage Facts Label (CFL) on pages 5-6 of the SBC, and the Uniform Glossary of Terms, are important transparency provisions included in the Affordable Care Act (ACA). If people with diabetes do not understand their insurance choices, they could find themselves in a plan that does not have adequate and/or affordable coverage. For example, the SBC could help a person with diabetes considering a plan with a very high deductible *understand* that he/she may have to pay a large amount money out of pocket before coverage starts.

The Association is pleased to see a diabetes management scenario was included in the proposed CFL template. The Association recommends a diabetes scenario be included in the final regulations because of the extraordinary and growing burden of diabetes in the U.S. Adequate and affordable insurance coverage is of paramount importance to people with diabetes. The SBC has the potential to better help people understand relative generosity of coverage when comparing plans.

We offer the following comments and recommendations on how the SBC, including the CFL, could be further refined and tested to ensure its accuracy and usefulness.

It is vital that people realize the costs in the “Sample Care Costs” and the “You Pay” sections of the CFL are not actually a person’s own costs or even their estimated costs, but rather gives an idea of how the plan might cover these medical scenarios generally and how much insurance protection a plan offers, in order to make comparisons among plans. HHS should test and continually monitor how consumers are reacting to and making decisions using the SBC and CFL medical coverage scenarios.

The Association recognizes there is a tension between keeping the SBC, including the CFL, simple and consumer-friendly but giving adequate detail so as to be accurate and not misleading. Providing additional relevant information in the “Managing Diabetes” scenario may be beneficial but should be consumer tested to ensure the CFL is helpful for consumers. Diabetes treatment is individualized, and depends on a person’s unique health profile, including the type of diabetes a person has. Thus, we recommend clarifying on the CFL that the “Managing Diabetes” scenario pertains to type 2 diabetes (as indicated on the Excel spreadsheet from HHS). We also think having further detail about the assumptions in the Managing Diabetes section could be beneficial, and there appears to be some room for this. We suggest a parenthetical under “Managing Diabetes” which might say: “Routine maintenance of type 2 diabetes including treatment with insulin and oral medications and self-testing twice a day,” similar to how a few assumptions of treatment are listed under the “Treating Breast Cancer” scenario. Also, we suggest indicating that treatment plans can vary greatly depending upon the type of diabetes, the course of diabetes in that individual and any complications (for instance, this could be done with an asterisk and a line at the bottom of the CFL, or on page 6 along with the other assumptions). These or any other changes should be consumer tested and monitored to ensure they are useful and not misleading, and to inform the development of the SBC. We recommend people should be able to access information about the detailed assumptions in the coverage scenarios elsewhere (for example, on a website).

In the glossary, the definition of Durable Medical Equipment (DME) includes “blood testing strips for diabetics.” We recommend that this language be modified slightly to read “blood testing strips for people with diabetes” to use person-first language. Departments invited comments on whether additional terms should be included in the glossary. We do think that additional terms defined in the glossary should include “pre-existing condition” and “pre-existing condition exclusion period” which are important terms for people with diabetes to understand.

Diabetes testing supplies are included under “medical equipment and supplies” in the details of the coverage scenario included on the Excel spreadsheet developed by HHS, and are indeed covered as durable medical equipment (DME) in some plans. However, some plans cover diabetes testing supplies under the prescription drug/pharmacy benefit. The DME definition in the glossary includes “Blood testing strips for diabetics.” We are glad to see this inclusion and do not think the definition should change. It is also consistent with the definition of DME in Medicare (Section 1861(n) of the Social Security Act). However, we recognize a potential for confusion for people with diabetes looking at the CFL if a plan covers diabetes testing supplies differently than what is indicated or inferred in the “Sample Care Costs” section (such as under a pharmacy benefit rather than as medical equipment and supplies). We recommend HHS further consider how variable coverage of certain items and services by plans might cause confusion among consumers when comparing plans and using the CFL, and whether

additional language should be developed and consumer tested. Sample language might include: “Your plan may cover diabetes testing supplies as DME, under a pharmacy benefit, or otherwise and you should check with the plan to learn details of coverage.”

The SBC will require additional scrutiny, refinement and continual study to ensure it is, and continues to be, useful to consumers over time. Thus, we recommend that HHS conduct further consumer testing, whether any changes are made to the SBC in the final rule or not. There should also be a continuous, annual review process to study, test, and refine the SBC and CFL, and collect data, to ensure it is useful for consumers, including people with diabetes. As part of the monitoring process, HHS should also assess to what extent plans are changing their benefit structures, and whether benefits changes could be attributable to new disclosure standards under the SBC. This could help monitor that the SBC requirement does not have the unintended consequence of adversely affecting coverage for diabetes.

Providing the SBC

We recommend that HHS require insurers to provide an accurate SBC product as soon as possible and feasible. The SBC should be provided as a stand-alone document and should be made visible among other plan documents. The SBC should not be embedded in the Summary Plan Description only, which could mean the SBC would not be seen by many consumers. In addition, we recommend that insurers and group health plans should make the SBC available on the internet. A person should not have to make a special request or provide personal information to get this information.

Final Considerations

We anxiously await the proposed federal rule on the Essential Health Benefits (EHB) expected later this year. The EHB regulations will be critically important to ensuring effective coverage options for consumers inside and outside the Exchanges, including millions of Americans with, and at risk for, diabetes. The Notice of Proposed Rulemaking on the Summary of Benefits and Coverage and Uniform Glossary does not address defining the EHB, but we wish to convey that, given the extraordinary burden of diabetes and prediabetes in the U.S., and the availability of effective treatments and therapies, the EHB must ensure adequacy of coverage so people with, and at risk for, diabetes can successfully prevent or manage the disease and its complications. While coverage necessary for people with diabetes falls across the 10 categories of the EHB included in the ACA, HHS should provide additional guidance to health insurers to ensure people with diabetes are not underinsured.

Thank you for the opportunity to comment on the Notice of Proposed Rulemaking: Summary of Benefits and Coverage and Uniform Glossary. Should you have any questions, please contact me at (703) 299-5528 or lmciver@diabetes.org.

Sincerely,



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