American Heart Association | American Stroke Association

July 5, 2012

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Submitted electronically via www.regulations.gov

RE: File code CMS-9965-P

Dear Secretary Sebelius:

On behalf of the American Heart Association (AHA), including its American Stroke Association (ASA) division, and more than 22 million volunteers and supporters, we appreciate the opportunity to offer our comments on issues related to the Department of Health and Human Service's proposed rule "Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans" (CMS-9965-P) and the associated information collection revising "Health Care Reform Insurance Web Portal Requirements" (CMS-10320).

The AHA/ASA has long advocated for all Americans to have access to affordable, adequate, quality health insurance coverage. This is critical to the AHA/ASA's goal of improving the cardiovascular health of all Americans and reducing cardiovascular and stroke mortality by 20 percent. Both the essential health benefits (EHB) package and the accreditation of qualified health plans (QHPs) will play important roles in making quality insurance coverage available to millions more people, and we welcome the Department's proposed rule specifically addressing these topics. We hope comprehensive regulations governing the EHB package and exchange quality rules will soon follow.

Collection of Essential Health Benefits Data

Purpose of Data Collection

We applaud the Department for issuing the proposed rule and revised information collection regarding collection of EHB data. Comprehensive data collection on the benefits covered by potential benchmark plans – and the ultimate benchmark selections – is vital to a better understanding of how the Department's intended approach to defining the EHB package could impact patients with heart disease, stroke, and other cardiovascular diseases (CVD).

Currently, public information about the benefits covered by potential benchmark plans is limited. Working jointly with the American Cancer Society Cancer Action Network, the American Diabetes Association, and the National Multiple Sclerosis Society, our affiliates have worked at the state level with their local insurance departments to try and gain a better understanding of the level of coverage available

in a number of the benchmark options, specifically the three largest plans in the small group market and the largest HMO plan. In addition to seeking to understand whether specific benefits are covered by these benchmark plan options, we also seek a greater understanding of what limits there might be on benefits. As you know, it is extremely difficult for interested consumers to identify these types of limitations based on information that is currently publicly available to them. HHS's proposed data collection revisions could go a long way toward collecting the type of information we seek about the impact of potential EHB benchmark options on patients with chronic disease.

The stated purpose of the proposed rule is to "collect sufficient information on potential benchmark plans' benefits to enable plans seeking to offer coverage in the individual or small group market in 2014 to know what benefits will be included in the EHB benchmark." We strongly encourage the Department to consider how else this information can and should be used and incorporate those uses into the stated purpose. Specifically, we recommend that this information be used for two distinct purposes:

First, this information should be used to help inform all stakeholders – including consumers – of what benefits may be included in the EHB benchmark. This will both enable them to play a meaningful role in deliberations over benchmark selection as well as prepare for 2014 themselves. Patients and consumers will be using the health plans and the coverage of certain benefits could have significant economic impacts on them and their families. Patients with chronic disease need to make major decisions that will depend on what is covered in the EHB. The sooner that information is available to consumers, the sooner they can make informed life decisions. Accordingly, we strongly recommend that all information that is collected under the proposed rule – including data on the default benchmark plan options for each state, state-selected benchmark plans, and state mandates – be made available without delay to the public via HealthCare.gov. We also hope that the Department will encourage and work with state policy makers to make any additional information about potential benchmark plans (in particular those not covered by this proposed rule) publicly accessible in a standardized format.

Second, this information should be used by the Department to ensure that potential benchmark plans meet statutory requirements, including nondiscrimination requirements, and that there are no unreasonable or arbitrary limits on the EHB package. The data collection being undertaken by the Department provides an opportunity to analyze potential benchmark plans to make sure they meet the statutory requirements. With this information, the Department can compare plans as well as identify existing plan designs that are discriminatory or do not meet the needs of diverse populations. The Department can then use this information to promulgate rules that ensure the EHB package itself does not include identified discriminatory components, as well as making sure that any allowed flexibility does not allow issuers to use discriminatory plan designs. We provide further discussion of limits throughout these comments.

Over the longer term, the Department should also consider how robust data collection requirements for states and carriers will be necessary to meet the Secretary's statutory obligation to periodically review and update the EHB package to address any gaps in access to coverage or changes in medical evidence or scientific advancement. It will also be necessary to inform the Department's evaluation of the benchmark approach for calendar year 2016 and to assess whether an alternative approach, such as a federally defined EHB, would better address access to care, consumer choice, risk selection, and the ACA's goal of establishing a minimum level of uniform benefits.

Data Specificity

The preliminary EHB bulletin did not define most of the ten statutory categories of required EHB services. Without clear definitions, it will be impossible to hold benchmark packages and health plans accountable for fulfilling a benefit category. Because traditional plans do not categorize their services within the same benefit categories or use the same terminology as the statute, without clear definitions of categories it is unclear how the EHB standards could be compared to potential benchmark plans to ensure that they comply with the ACA.

For example, "ambulatory patient services" is not a category that is commonly seen in commercial plans, and it is unclear what specifically would need to be covered to satisfy the Department's standards. In addition, other items and services, such as cardiac rehabilitation, durable medical equipment, hospice or skilled nursing services, and certain preventive services may fall under multiple categories or may not fit neatly within any single category. To further illustrate, tobacco cessation pharmacotherapy may be listed under prescription drugs (or not be covered at all) and tobacco cessation counseling may fall under preventive services. Other smoking cessation aids, such as patches, gums, and nasal sprays, may fall under preventive services or fall through the cracks. Other screening tests (e.g. lipid panel, A1c) may fall under either preventive services or laboratory tests, depending on whether it's being used for routine screening or diagnostic or monitoring purposes.

We commend the inclusion of "outpatient rehabilitation services" and "habilitation services" as listed services on which certain potential benchmark issuers will have to provide information, including information about coverage limitations. We caution, however, that "habilitation benefits" in particular is a little understood term that covers a broad array of services. We are concerned that by listing the broad category without detailing an explanation of the benefit and common habilitation services, and the settings under which these services are provided, HHS risks losing a critical opportunity to collect adequate information to help determine this essential benefit. Therefore, we strongly recommend that HHS insert in the data collection chart the National Association of Insurance Commissioners' definition of habilitation services[1] and add sub-rows specifying benefits that commonly fall under this benefit category (and that are included in the NAIC definition). In addition, we encourage the Department to specify that cardiac rehabilitation services fall within the category of outpatient rehabilitation services.

To move towards greater standardization and thus more clarity, we strongly encourage the Department to collect as detailed information as possible on potential benchmark and state-selected benchmark plans and to determine a methodology for mapping benefits to the EHB categories.

Section 2713 Preventive Health Services

We were very pleased that the Department clarified that the Section 2713 preventive health services are part of the EHB in the February FAQs. Because these preventive health services are part of the EHB, we expect the Department to collect all data elements on the Section 2713 preventive health services, including specific services such as tobacco cessation (and within

[1] The NAIC defines "habilitation services" as "Health care services that help a person keep, *learn* or improve skills and functioning for daily living. Examples include therapy for a child who isn't walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings." This definition was adopted by HHS for inclusion in the Glossary of Terms developed under Section 2715 of the ACA.

tobacco cessation, specific services recommended by the U.S. Preventive Services Task Force, such as counseling and prescription and over-the-counter tobacco cessation pharmacotherapy), through the EHB data collection process. While the proposed rule focuses on data collection to support standards related to the EHB, we remind the Department that, although the Section 2713 preventive health services are being incorporated into the EHB, there are additional statutory requirements and standards that must be met.

The ACA requires that group health plans and health insurance issuers offering group or individual health insurance provide coverage of these services and not impose any cost sharing requirements on them. The statute is very clear on the process for defining and updating these services and their definition is outside of the EHB process. The recommendations that define these services may include recommendations of how often a certain preventive services should be provided. Given the incorporation of such details in the definitions of these services, any limits allowed as a part of the EHB cannot be applied to the Section 2713 preventive health services. The Department should use the data collected pursuant to this rule to ensure the statutory requirements of Section 2713 are met in each of the benchmark plans.

Data on Benefit Limits and Exclusions in Potential Benchmark Plans

We have previously expressed concerns about the lack of information available on limits in the potential benchmark plans and how limits could impede access to items and services included in the EHB package. Information about quantitative and non-quantitative limits is not readily available and without it, patients cannot be assured that all benchmarks will have reasonable, non-discriminatory limits that are truly within the scope of the typical employer plan.

Accordingly, we are glad to see that the Department proposes collecting information on different types of limits. At the same time, while we believe this information is important to have, these limits should not be incorporated wholesale into the EHB package. Arbitrary and unreasonable limits could be used to restrict needed care – inconsistent with the ACA's clear intention to guarantee that at least the ten benefit categories are consistently covered – or steer consumers into or away from certain plans. In some instances, arbitrary service limits could seriously interfere with necessary care. For example, heart attack and stroke patients frequently face arbitrary quantitative limits on the amount of cardiac rehabilitation or physical, speech, and occupational therapy services they can receive, even when such care is medically necessary for their continued recovery.

We are also concerned that it will not be possible to verify the actuarial equivalence of treatment limits. This could result in some plans using non-quantitative limits to reduce access to benefits while still appearing to be actuarially equivalent to the benchmark plan. This is of particular concern in regard to non-dollar limits established in place of previously existing dollar limits. The Department's FAQs on the EHB Bulletin allow dollar limits in state mandated benefits or other benefits to be converted to non-dollar limits that are at least actuarially equivalent to the dollar limits. But it is not clear that a determination of actuarial equivalence can be made for a specific benefit limit (as opposed to a package of benefits and cost-sharing). And even a limit that is actuarially equivalent when measured for a standard population could be grossly inadequate for many individual consumers.

We recommend that the Department use the data collected to understand quantitative and non-quantitative limits and how they may be discriminatory and/or limit access to EHBs. Additionally, given the Secretary's obligation to ensure that the EHB package does not discriminate and to comply with the requirements in Sections 1302 and 1557, we believe this data should be used to identify any quantitative or non-quantitative limits as well as exclusions that might be discriminatory

and to ensure that they do not become part of the EHB package. This is particularly a concern when the limits or exclusions are condition-based.

Data on Rider Policies

The guidance on the issue of whether rider policies will be considered as part of the EHB benchmark is confusing and inconsistent. In the FAQs on the EHB guidance, the Department states the following:

> "For purposes of identifying the benchmark plan, we identify the plan as the benefits covered by the product excluding all riders. HHS intends to propose that if benefits in a statutory category are offered only through the purchase of riders in a benchmark plan, that required EHB category would need to be supplemented by reference to another benchmark."[2]

Yet, a footnote in the guidance states:

> "Nomenclature used in HealthCare.gov describes 'products' as the services covered as a package by an issuer, which may have several cost-sharing options and riders as options. A 'plan' refers to the specific benefits and cost-sharing provisions available to an enrolled consumer. For example, multiple plans with different cost-sharing structures and rider options may derive from a single product."[3]

If a plan is, in fact, a product that is supplemented by optional rider policies, then it is very confusing for the Department to define a plan in its FAQ as a product without riders. Individual plans that emerge from a single product are, by definition, distinguished by the availability of rider policies.

As proposed, the Department intends to collect data from the issuers of the largest three products in each state based on the plan with the highest enrollment within the product. We urge the Department to require the collection of data related to the rider policies made available by that plan. High enrollment in a plan can be attributed, at least in part, to the availability of rider policies and is therefore information that HHS must have in order to develop a policy that reflects the statute's requirement that the scope of benefits reflect a "typical employer plan." This information is especially important to patients, as prescription drugs are often covered through riders.

State Submission for State-Selected Benchmarks

Appendix G of the information collection includes instructions for submission of data on State-selected benchmarks. The Department proposes collecting all of the information requested from issuers, as well as information on the type of benchmark selected, which ACA categories are covered, and whether the state is supplementing the benchmark plan with benefits from another plan option for one or more of the EHB categories. The Department also proposes an alternative approach for a state that selects as its benchmark one of the three largest small group market benchmark options, from which the Department will already have collected data. However, it notes that if the state chooses the alternate option, the Department will ensure coverage in all ten statutorily required categories.

We assume that the Department will fill in the required categories in a robust way that ensures plan enrollees receive the comprehensive benefits intended by the ACA. However, as this alternate approach appears to be a new idea, we request further clarification on how the Department would

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[2] http://cciio.cms.gov/resources/files/Files2/02172012/ehb-faq-508.pdf
[3] http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf, page 4.

supplement the ten categories to ensure access to the full scope of EHBs. The approach should use a transparent process when supplementing the ten categories under this approach with an opportunity for stakeholder input. We also request clarification on whether there will be any action taken by the Department to verify coverage of all ten categories when states do not choose the alternate approach.

Accreditation of QHP Issuers

General Approach

Accreditation is a critical tool for ensuring that health plans are providing high quality care and good customer service. Nationally recognized accreditation can act as a seal of approval that gives consumers and employers confidence in the product they are purchasing. It can also be used by issuers themselves to identify areas for improvement. Indeed, a significant number of health plans have already demonstrated their commitment to quality by voluntarily obtaining private accreditation and publicly reporting enrollee experience and clinical outcomes.

To ensure that accreditation continues to be a meaningful tool over time, we generally support the Department's proposed approach to recognizing accrediting entities in two phases. In particular, as we discuss in more detail below, we strongly support requiring accrediting entities to meet specific conditions for recognition in phase one and to go through a more robust and transparent application process in phase two. In both stages, a driving principle should be assuring that, regardless of which entity a plan is accredited by, consumers are able to use accreditation information to make meaningful, apples-to-apples comparisons of QHPs.

It is also important to recognize that under current regulations and guidance, accreditation is essentially being utilized as a proxy for assuring quality in the early years of QHP certification. We recognize the many demands placed on the Department and on states in getting the exchanges up and running and we acknowledge the complexity of developing effective, standardized quality ratings and quality improvement initiative standards for QHPs. However, we strongly believe that accreditation should not be considered a permanent substitute for the broader quality requirements on exchanges and health insurance issuers. The Department should clearly distinguish these requirements in future guidance and continue to move forward as swiftly as possible on implementing the range of exchange quality requirements included in the ACA.

Phase One

The proposed rule states that HHS intends to recognize the National Committee for Quality Assurance (NCQA) and URAC as QHP accrediting entities so long as they demonstrate that they meet a set of conditions. We are unaware of any other entities that meet the statutory requirements at this time. While we are generally supportive of the specified conditions, below we provide specific comment on some of the conditions for recognition.

Quality Measures

We strongly support the proposed requirement that recognized accrediting entities must assess local performance on clinical quality measures, such as Healthcare Effectiveness Data and Information Set (HEDIS), and patient experience ratings on a standardized Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. HEDIS and CAHPS are national standardized tools used to, respectively, measure performance on important dimensions of care and service, and assess patients' experiences of care.

We also favor requiring accreditors to use a standardized set of quality metrics – with the ability to "drill down" to the specific measures – to ensure comparability across QHPs. All commercial QHPs, irrespective of product type (e.g. HMO, HMO/POS, PPO), and Medicaid QHPs should be required to report on the same measures in the same way.

Measures should be based on national standards, the primary sources of which should be measures endorsed by the National Quality Forum (NQF). When non-NQF measures are used because NQF measures do not exist, it should be with the understanding that they will be replaced by comparable NQF endorsed measures when available. Where NQF-endorsed measures do not exist, the next level of measures that should be considered, to the extent practical, should be those endorsed by other entities with a consensus process for developing and approving measures, such as national accrediting organizations such as NCQA or The Joint Commission and federal agencies.

In addition, we strongly recommend prioritizing measures that are being used concurrently by public and private sector purchasers and payers. Purchasers in the private sector, as well as states serving as purchasers for their public employees and Medicaid enrollees, are using innovative tools to assess the quality and value of health plans when making contracting decisions. We believe that in order to drive the alignment necessary to truly improve quality and reduce costs across the board, these purchasers, along with exchanges, must "row in the same direction," and use – wherever possible – the same quality measures to hold health plans accountable.

Level of Accreditation

The proposed rule requires recognized accrediting entities to provide separate accreditation determinations for each product type (e.g. HMO, POS, and PPO) offered by a QHP issuer in each exchange (for example, exchange HMO, exchange POS, and exchange PPO) based on data submitted by the issuer that is representative of the population of each QHP in that exchange product type. We appreciate the Department's clear statement on this point, as we believe it has been a source of confusion in the past (for instance, the General Guidance on Federally Facilitated Exchanges indicated that QHP accreditation would be confirmed at the issuer level). In order to facilitate comparisons based on quality and transparency, we believe it is important that accreditation is assessed at least at the product level. We also encourage the Department to consider whether it would be feasible to move towards accreditation at the QHP level in phase two.

Phase Two

The proposed rule indicates that the Department plans to establish a comprehensive, public process for recognizing accrediting entities in phase two. We strongly support this decision and, as noted previously, encourage the Department to clearly indicate when phase two is expected to begin. We believe the standards for recognition can and should be used to help move us closer to a high value, patient-centered health care system rather than to reinforce the status quo. However, for this to happen, the Department will need to clearly outline these standards with sufficient advance notice for potential accrediting entities to make any necessary updates to their programs. In particular, we encourage the Department to require that accrediting entities review a number of health plan processes important to consumers, including but not limited to those related to marketing practices, member privacy, and language access services. In addition, accrediting entities should assess health plan efforts to reduce health care disparities and provide culturally competent services.

We also support the Department's proposal to incorporate public participation in the recognition process. This should include both public input on the development of application procedures and

standards as well opportunities for the public to provide written and/or oral comment on applications from potential accrediting entities.

Finally, we urge the Department to regularly update its accreditation standards over time, especially as delivery and payment system reforms catalyzed by the ACA begin to take root and new ways of measuring health care quality and patient experience are developed.

Data Sharing Requirements

The proposed rule requires that recognized accrediting entities must provide data from a QHP issuer's accreditation survey to the exchange in which the issuer plans operate. We support this requirement – in particular, we believe it is critical for the exchange to have access to accreditation status or level, accreditation score, and clinical quality measure results and adult and child CAHPS measure survey results. However, we recommend that recognized accrediting entities should provide the exchange a copy of the most recent accreditation survey report for each accredited product as well as any corrective action plans and summaries of findings. We also urge the Department to require that recognized accrediting entities must provide any additional information at their disposal on the QHP issuer's policies, procedures, or performance upon request from an exchange. This is particularly important if accreditation status will be used to satisfy any additional QHP certification requirements, such as network adequacy standards.

While not addressed in this proposed rule, we believe it is critical that exchanges post accreditation status or level and score on their websites. If, in the early years, a QHP issuer is not yet accredited, this fact should also be publicly reported along with information on what accreditation means. Consumers and purchasers of care want and need to know about health plan quality and level of accreditation. In the final rule, the Department should clearly authorize public reporting of accreditation data submitted to exchanges.

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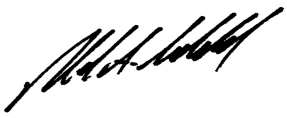
Thank you again for the opportunity to share our comments on these issues related to the collection of EHB data and the accreditation of QHPs. If you have any questions, please feel free to contact Stephanie Mohl, Government Relations Manager, at Stephanie.Mohl@heart.org or 202-785-7909.

Sincerely,



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