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December 22, 2014

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health and Human Services
ATTN: CMS-9944-P
PO Box 8016
Baltimore, MD 21244-8016

RE: File Code CMS-9944-P (Notice of Benefit and Payment Parameters for 2016)

Dear Secretary Burwell:

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 this opportunity to submit comments on the Department of Health and Human Services' (HHS) proposed rule, "Notice of Benefit and Payment Parameters for 2016."

The AHA/ASA has long advocated for all Americans to have access to affordable, quality health insurance coverage. Access to affordable, quality health care is critical to helping the association achieve its ambitious goal to prevent as many heart attacks and strokes as possible, as well as reduce the risk factors for these conditions.

We applaud HHS for addressing a number of concerns that we've raised previously about the issues that patients have using their health insurance coverage. While more work remains to be done to ensure that the Affordable Care Act (ACA) fully meets the promise of providing affordable, adequate, transparent access to health care, this proposed rule continues to move in the right direction. Although this rule covers many important topics, we have focused our specific comments below on a number of issues that we believe are particularly critical to people with heart disease or stroke or who need to prevent these conditions.

Definitions (§144.103)

HHS proposes to define the term ''plan'' so that it means, with respect to an issuer and a product, the pairing of the health insurance coverage benefits with a particular cost-sharing structure, provider network, and service area. This definition would make clear that plans that differ in their cost-sharing requirements (such as copayments, coinsurance or

deductibles), or that have different networks of contracted providers or different service areas, are considered to be different plans. This new definition of plan is better aligned with what a consumer buys: a package of benefits, with a cost-sharing structure and provider network that operates within a service area. Within a metal level, the cost-sharing structure and provider network make a big difference in price, and so it is appropriate to review plans at this level.

Annual Eligibility Redetermination (§155.335)

HHS is proposing to implement an alternative approach to re-enrollment of consumers through the federally facilitated Marketplace (FFM). Under this proposal, people would be offered a choice at the time of initial enrollment of being re-enrolled into a different, lowest premium plan when the time comes for renewing their coverage. We agree that there needs to be a default process for auto-renewing people. We share HHS's goal of keeping as many people insured as possible. However, the proposed change to the re-enrollment methodology has profound implications for consumers with Marketplace coverage, particularly given that the experience based on the current open enrollment period so far, as well as experience in Medicare and the Federal Employees Health Benefits Program, indicates that only about 15 percent of people switch plans in a given year and the vast majority instead rely on auto-enrollment to renew their coverage.

While we appreciate that price of coverage is a very important factor for some consumers, in many states placing consumers into the lowest premium plan by default would mean a change in their insurer. This represents a significant departure from current common practice in workplaces and Medicare, where consumers are auto-enrolled into their current coverage, offered by their current insurer. Consumers may have many reasons for wishing to stay with their current insurance company, such as a desire to keep their current provider network or coverage for specific medications.

We are also concerned that this approach only focuses on premium costs and ignores other costs the consumers will be required to pay out-of-pocket, including cost-sharing and out-of-network expenses. A consumer, particularly one who needs considerable health care treatments, could be automatically enrolled into a plan that has a lower premium but may actually end up paying more during the year because deductibles, co-pays and co-insurance, and out-of-pocket limits are higher.

Communicating the consequences of choosing this form of auto-enrollment to consumers will be very difficult. Consumers may not fully understand the ramifications of their choice until their coverage starts the next calendar year and they start using their coverage. HHS may want to consider giving enrollees the opportunity to revise their auto-renewal default choice through their healthcare.gov account prior to the next open enrollment period. We also recognize that individuals would still have the opportunity to switch from the plan into which they were auto-renewed during the open enrollment period, but again, experience has shown that most consumers don't return to shop for coverage, even when it would be in their best interest to do so.

Given the potential ramifications of this change, we strongly encourage HHS to conduct consumer testing before making any change to the re-enrollment choice hierarchy. It is important for HHS to fully appreciate what re-enrollment option consumers would prefer and how to express that option during the enrollment process in consumer-friendly

language so that people understand their choices and the consequences of being auto-enrolled into a plan that could be significantly different from their current coverage. Consumer-testing should also assess the best way to continue to communicate to consumers the importance of being active shoppers and returning to the Marketplace each year to find the plan that best meets their needs, rather than relying on auto-renewal, whatever the default.

HHS also asked for comments on whether to permit state-based Marketplaces to have the flexibility to implement these or alternative re-enrollment hierarchies. We would favor allowing states to adopt alternate hierarchies as a means of testing different options prior to making them available in a more widespread manner.

Special Enrollment Periods (§155.420)

We applaud HHS for the changes it is proposing with respect to special enrollment periods (SEPs) and make a number of suggestions for additional SEPs.

In particular, we support the amendment that would allow people who know they will lose minimum essential coverage due to a permanent move to have advance access to the SEP, rather than having to wait to complete their move. As we noted in previous comments urging HHS to expand advance access to a SEP, this policy helps consumers minimize or avoid gaps in health insurance coverage.

We also support HHS's proposals to create additional SEPs, similar to what we recommended last spring. Specifically, we strongly support the new SEP for consumers in a non-Medicaid expansion state who were previously ineligible for the premium tax credit solely because their income was below 100 percent of the poverty level but who become newly eligible for tax credits because of a change in their income. Because of their low incomes, many people in the Medicaid coverage gap will unfortunately likely remain uninsured. But for those people who experience an increase in income during the year that would make them eligible for premium tax credits, we agree that it is very important for them to have this option for obtaining affordable health insurance coverage, rather than having to wait for the annual open enrollment period.

We also support the proposal to create a SEP for individuals and their dependents who are covered under a group or individual plan that is not offered on a calendar year basis. People with this coverage could have their plan come up for renewal outside of the annual open enrollment period, which would either lock them into that coverage even if it no longer meets their needs or is unaffordable or require them to go without coverage until the next open enrollment period. By allowing them a SEP, such consumers will have the opportunity to enroll in Marketplace coverage if it better meets their needs without having a gap in coverage.

Finally, we support the new SEP for those enrolled in Marketplace coverage who lose dependent status or who lose a dependent due to divorce, legal separation, or death. While this will be very helpful to people with Marketplace coverage who experience these types of life changes, we recommend also making this SEP available to others who face a change in their family structure and could benefit from being able to choose a health plan that fits their new circumstances.

HHS also requested comments on other situations that may warrant a SEP. We recommend creation of SEPs for consumers in the following situations:

- *People who rely on materially inaccurate provider directory information when choosing a Marketplace plan.* Unfortunately, inaccurate provider directories continue to be a significant concern for consumers. While we appreciate that HHS is taking steps elsewhere in this rule to help make provider directories more accurate and up-to-date, we are concerned that errors will persist. Consumers who make an effort to choose the right plan based on the information they reviewed in the directory should not be trapped in that plan if it turns out that their doctor, hospital, or other health care provider is not part of their plan's network. There are serious implications for consumers if they choose a plan believing the doctors or providers they need are part of the network and then find out later that they are not, including continuity of care concerns and adverse financial consequences.

- *People with an acute or chronic disease or condition who are in the midst of active treatment who lose affordable access to their treating health care provider due to a mid-year change in their plan's network.* Patients undergoing treatment for an acute or chronic disease who chose a plan with the expectation that their doctors or other needed health care providers are in-network can find themselves in a dilemma if their provider leaves their plan's network or is moved to a higher-cost provider tier midway through the plan year. These patients are forced to choose between continuing to see their trusted provider but at significantly higher out-of-pocket costs or switching to a provider who is not familiar with them or their condition. While we recognize that some insurers may provide "continuity of care" coverage, such coverage is not guaranteed and the length of such coverage is often inadequate.

- *People who lose access to a needed prescription drug due to a mid-year change in their plan's formulary.* Likewise, patients who choose a plan based on its coverage for a particular necessary medication are caught in an untenable situation if the drug is dropped from the plan's formulary or moved to a higher cost-sharing tier. Such changes can make the medicine unaffordable. While we recognize that some patients may be able to continue to access their medication through the plan's exceptions process, providing a SEP gives consumers another remedy for their situation, particularly if their exception request is denied.

Provision of EHB (§156.115)

We applaud HHS for proposing to establish a uniform definition of habilitative services and remove the provision that gives issuers the option to determine the scope of habilitative services. As we have commented previously, we think it is critically important that HHS do more to ensure adequate coverage of habilitative services by health plans by adopting a uniform definition. We believe that such a definition should serve as a federal floor for defining habilitative services. While we agree that states should have the flexibility to define habilitative services in a manner at least as strong as the federal definition, states with weaker definitions than the uniform federal definition should be required to either strengthen their definition or use the federal definition. Such a policy is

consistent with the general pre-emption standard in the ACA, in which states are allowed to be more protective of consumers but cannot impose weaker protections.

HHS is seeking comments on three options for the definition of habilitative services. The AHA/ASA supports the second option of defining habilitative services based on the definition from the Glossary of Health Coverage and Medical Terms that was developed for HHS by the National Association of Insurance Commissioners (NAIC)[1], as we have previously recommended. However, we note that the definition included in the proposed rule is not the full definition adopted by the NAIC. In addition, we recommend the addition of devices to the uniform definition, since devices are specifically included in the statute and the proposed rule.

HHS also proposes prohibiting plans from imposing limits on coverage of habilitative services that are less favorable than any such limits imposed on coverage of rehabilitative services. HHS notes in the preamble to the rule that: "Since the statutory category includes both rehabilitative and habilitative services and devices, we interpret the statute to require coverage of each. Therefore, issuers that previously excluded habilitative services, but subsequently added them, would be required under our proposal to impose separate limits on each service rather than retaining the rehabilitative services visit limit and having habilitative services count toward the same visit limit."

Unfortunately, we've seen Summaries of Benefits and Coverage (SBCs) for many plans that indicate that both rehabilitative and habilitative services count toward the same visit limit. We agree with HHS that separate limits are better than a single limit, and therefore, we support this clarification. We note, however, that in many cases, even with separate limits, the caps on rehabilitative and habilitative services are inadequate and in our view violate requirements that essential health benefits (EHB) benefit design not be discriminatory. We will discuss this in greater detail later in our comments.

While we appreciate that HHS is proposing steps to define more clearly habilitative services, we once again encourage you to also more clearly define the types of services that are included as rehabilitative services. **Specifically, we strongly urge you to clarify that cardiac rehabilitation (CR) is required to be covered as a rehabilitative service. CR has received a class I recommendation in the American College of Cardiology Foundation/American Heart Association guidelines (which means the treatment is useful and effective and should be performed) for patients following heart attack, coronary artery bypass surgery, heart failure, or other cardiac events**. CR helps restore and enhance cardiac function, slows or even reverses the progression of cardiovascular disease, and reduces the risk of a future cardiac event. Despite the proven benefit of CR, it is often unclear whether it is covered under the rehabilitative benefit. Many SBCs are silent on whether cardiac rehabilitation is covered under rehabilitation services or under another category of coverage and whether there are any limits on this coverage. It is important that heart disease patients know when choosing a plan whether CR is covered and under what conditions.

[1] The NAIC defined "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."

Finally, we greatly appreciate the May 2, 2014 “Frequently Asked Questions” guidance that HHS put out establishing clear, more specific minimum standards for the tobacco screening and cessation services that insurance companies must cover each year without cost-sharing. We urge you to consider codifying this guidance in regulations as part of ongoing efforts to better define the EHB.

Collection of Data To Define Essential Health Benefits (§156.120)

We support HHS’s proposal to allow each State to choose from 2014 plans to select a new EHB base-benchmark plan for the 2017 plan year. We appreciate the recognition that benchmark plans used to determine the essential health benefits for each state need to be updated. Basing them on 2014 plans is an improvement, nonetheless, we would prefer to see a different process identified to determine essential health benefits, one that better meets patient needs and is more consistent across the country. However, since an alternative approach is not being proposed at this time, and HHS is continuing to use the benchmark process to define EHB for each state, we support using 2014 plans as the benchmark, but would like to see this implemented beginning for the 2016 and not the 2017 plan year. Allowing each state the opportunity to select a new EHB base-benchmark should open the door for inclusion of benefits, such as obesity treatment, that are often either not covered in the current benchmark plans or are covered inadequately. We also support the collection of new benchmark plan data, including administrative data and descriptive information pertaining to all health benefits in the plan, treatment limitations, drug coverage, and exclusions.

We also want to take this opportunity to strongly urge HHS to review the EHB benchmark approach as soon as possible. In previous rules and guidance related to EHB, HHS had indicated that it intended to revisit the benchmark approach for the 2016 plan year and beyond. Moreover, the ACA requires the HHS Secretary to periodically review the definition of EHB, report the findings of the review to Congress and the public, and update the EHB as needed to address gaps in access to care or advances in the relevant evidence base. While we recognize that EHB has only been in effect for 2014, we are disappointed that HHS is planning to continue the benchmark approach through 2017 without first conducting a thorough evaluation of whether this approach is adequately meeting the needs of patients and consumers.

We recommend that HHS make evaluation of EHB and the benchmark approach a top priority immediately so that the results of this review may help inform the method for defining EHB for the 2017 plan year and beyond. The Association supports the creation of an ongoing advisory committee or council that would monitor the EHB implementation and make recommendations for updating the EHB package to address gaps in coverage and to evaluate benefit designs and service trends. This approach would also allow the EHB package to be adjusted to reflect advances in medical evidence or scientific advancement. The advisory panel should include experts with a wide range of medical expertise that represent the health care needs of diverse segments of the population.

Prescription Drug Benefits (§156.122)

HHS is proposing significant changes in the prescription drug benefit requirements for plans that must cover the EHB. Specifically, HHS proposes replacing the drug count standard with a requirement that plans adopt a pharmacy and therapeutics (P&T) committee and use that committee to ensure that the plan's formulary drug list covers a sufficient number and type of prescription drugs. The proposed rules include specific requirements that P&T committees would be required to meet. HHS also asks for comment on whether to replace the U.S. Pharmacopeia (USP) standard in the current regulations with a standard based on the American Hospital Formulary Service (AHFS). And HHS also seeks comments on how to use either AHFS or the USP classification systems to develop a minimum standard for issuers to meet either in addition to or as an alternative to the use of P&T committees.

In general, the Association favors adoption of the P&T committee approach, with a quantitative drug count standard as a floor to ensure that plan formularies cover the range of prescription drugs that patients may need. We note that the P&T committee approach is already widely used in the health insurance industry and is the approach used by Medicare Part D. We support the standards included in the proposed rule requiring P&T committees to ensure that an issuer's formulary drug list:

- Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and does not substantially discourage enrollment by any group of enrollees; and

- Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and which are indicative of, and consistent with, general best practice formularies currently in widespread use.

In addition to these requirements, we recommend that HHS amend the proposed rules to also give P&T committees the following duties:

- Review and make recommendations for issuer placement of drugs within specific tiers; and

- Review issuer medical utilization policies, such as prior authorization requirements and quantity limits, to ensure that they are appropriate for the specified drugs and the patient's condition for which they are prescribed.

In subsection 156.122(a)(iii)(D), we recommend including a specific timeframe by which the committees should review newly approved drugs and make a determination on their inclusion and placement in the issuer's formulary.

We also recommend that HHS make a number of changes to the proposed rule with respect to the size and membership of the committees. These recommendations are largely based on experience with Medicare Part D and the HHS Inspector General's

findings in a March 2013 report[2] about shortcomings with P&T committees and HHS's oversight of these committees by private Medicare prescription drug plans. More specifically we suggest the following:

- HHS should require a minimum number of members serve on the P&T committees. While we recognize that the membership standards proposed in the rule would require that committees have "members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees," we are concerned that this may be too vague. The OIG report pointed out that some of the P&T committees used to determine Medicare Part D formularies are as small as 3 people. Requiring a minimum number (such as 16, the average size of Medicare Part D P&T committees) would further help ensure diversity of opinion and clinical experience. HHS should also ensure that the committees are multidisciplinary and consider the needs of special populations, such as children, pregnant women, and the disabled.

- HHS should spell out in more detail the definition of a conflict of interest for committee members and specify when members should recuse themselves from decision-making (discussion as well as voting) and increase the threshold of members who are free of conflict. In particular, we believe that the proposed requirement that only 20 percent of committee members have no conflict of interest with industry is too low. While we recognize that it can be difficult to form an expert panel devoid of industry relationships, we urge HHS to consider requiring that a majority of committee members, including the chair, be free of significant conflicts. We also recommend that HHS revise subsections 156.122(a)(i)(C) and 156.122(a)(i)(D) to include pharmacy benefit managers among the types of entities with which committee members cannot have a conflict of interest.

- We also support the requirement in the proposed rules that P&T committees meet at least quarterly and maintain written documentation of the rationale for all decisions regarding formulary drug list development or revision. We recommend requiring that the written documentation be made publicly available on the issuer's website.

With respect to whether to use the AHFS or USP classification systems, there are advantages and disadvantages to both. The USP system undergoes more rigorous review, but it is not updated as frequently as the AHFS system. As a result, there is sometimes a lag in adding new medications. In addition, the USP system contains only two tiers (category and class), so it is less detailed. Conversely, the AHFS system is updated at least annually, and with its four tiers, it is more detailed. A quantitative standard that required that at least one drug per AHFS third-tier category be included in plan formularies could provide for better coverage for cardiovascular disease patients in certain instances. For example, under the USP standard to cover one drug in each class, all of the antiarrhythmia drugs are grouped together in the same class, so plans may be required to cover only one such drug. However, different drugs work for different

[2] Department of Health and Human Services Office of the Inspector General. "Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions." March 2013. Accessed online at: https://oig.hhs.gov/oei/reports/oei-05-10-00450.pdf

types of arrhythmias so that could mean that consumers with some types of arrhythmias might not have a drug on their plan's formulary that works for their specific condition. However, under the AHFS system, there are seven sub-categories in the third tier for each type of arrhythmia, so under a standard that required coverage for one drug in each third-tier category, there would be greater assurance that patients would have coverage for a drug for their specific type of arrhythmia. Having said that, requiring inclusion of at least one drug for some third tier sub-classes could result in drugs being unnecessarily included in the formulary.

Regardless of the classification system ultimately chosen, we encourage HHS to ensure that the most recent version is used by issuers each year. In addition, we would support retaining the current standard of the number of drugs covered in each category or class by the benchmark plan *or* at least one drug per class or subclass using either the AHFS or USP system, whichever is greater, in conjunction with the expert recommendations of the P&T committee.

We also take this opportunity to raise another issue with respect to prescription drug coverage. The current regulations indicate that drugs counted as part of the EHB benchmark standard for plan formularies must be "chemically distinct" from one another. This creates a concern for medications that have different delivery mechanisms. For example, nicotine-replacement-therapies (NRTs) used for tobacco cessation all contain nicotine, but they use different mechanisms of bringing nicotine into the body. This difference in mechanisms is crucial when treating nicotine addicts with different levels of addiction. For instance, someone who is heavily addicted may need to use the nasal spray or inhaler, which delivers nicotine into the blood stream much quicker than the patch or gum. It is important that smokers wanting to quit have more than one NRT available to them, and treating NRTs as chemically indistinct will not guarantee this. If NRTs are chemically indistinct, then a benchmark plan covering all five available NRTs would only be counted as covering one – therefore allowing other EHB plans to cover only one. Therefore, we urge HHS to implement a standard that goes beyond "chemically distinct" and recognizes that medications with different delivery mechanisms are distinct items on formularies.

On a different issue, qualified health plans (QHPs) currently are required to have an "exceptions process" in place for enrollees to request and gain access to clinically appropriate drugs that are not covered by the plan. We applaud HHS for proposing additional standards that plans must meet with respect to this exceptions process, including specifying the timeframes in which plans must act on these requests, as we recommended in earlier comments. We also appreciate HHS adding an independent, external review process when the initial exceptions request is denied. HHS and other regulators should monitor the frequency with which this independent review process is needed and plan decisions are overturned to ensure that plans aren't routinely denying consumer requests.

In addition, we support the clarification that, once an exception has been granted, plans should honor it for the duration of the prescription, including refills. For patients who have chronic medical conditions and have medications that they must take long-term, we encourage HHS to consider requiring that the exception remain in place for the duration of the patient's need for the medication. Patients would still be required to get a new prescription from their health care professional at least annually – which would allow

patients and their clinicians to reevaluate whether the medicine is still needed and working as intended – but by eliminating the need to also submit the exceptions request when the prescription is renewed, HHS would be eliminating an unnecessary barrier to care. Finally, we are extremely pleased that HHS is clarifying that patient cost-sharing for excepted drugs count toward the maximum out-of-pocket limit.

There is an additional protection for consumers that we urge HHS to consider: prohibiting plans from deleting drugs from their formulary mid-year or moving them to a higher cost-sharing tier (with some exceptions for some limited circumstances, such as when a drug is found by the FDA to be unsafe or it is switched to over-the-counter status). Many patients needing certain medications carefully choose a plan to ensure they will have coverage for them but are then trapped in a plan that no longer meets their needs if their insurance company removes the drug from the formulary.

We are also very supportive of the proposals to increase formulary transparency. In order for patients to select the plans that best meet their individual health care needs, they must have access to easy-to-understand, detailed information about formularies, and the costs of medications. While we have seen some transparency improvements with the 2015 plans, many plans still do not have a direct link to a plan's formulary on the SBC as required by the ACA. In order to find the formulary, multiple searches must be conducted for some plans. The proposed rule reiterates the ACA requirement and proposes that each plan publish up-to-date, complete formularies with information about tiers and any restrictions on accessing the drug. HHS is also seeking comment on whether formulary tier information should include cost-sharing information, such as the pharmacy deductible, if any, and cost-sharing. We are supportive of all of these common-sense proposals that help patients understand and utilize their coverage. However, since plans are employing the use of co-insurance more frequently, plans should detail what the actual patient cost-sharing would be in dollar terms. Co-insurance percentages are often meaningless to patients since they have no way of knowing how the percentage translates to how much they will have to pay for a drug or service.

We also are very supportive of the proposal to require plans to submit drug formularies in machine-readable file. Currently, there is no standard formulary design and some have search capabilities while others do not. We would very much like to see an interactive web tool such as a plan finder or benefit calculator that matches an individual's prescription needs with appropriate plans, such as exists for the Medicare Part D program. Submitting information in a standard machine-readable format can assist in developing such tools.

Prohibition on Discrimination (§156.125)

We applaud HHS for including language in the proposed rule's preamble that reminds plans they must not design plan benefits in a discriminatory manner, by for example placing limits on or excluding services. We are particularly pleased that HHS singled out the needs of patients with chronic conditions by writing, "We also caution issuers to avoid discouraging enrollment of individuals with chronic health needs."

In addition to the examples HHS identified in the preamble, the American Heart Association has seen a number of different plan designs that we believe discriminate against patients with chronic or disabling conditions and/or serve to discourage

enrollment of individuals with chronic health needs. As part of the plan review process for 2015, we had hoped there would be a better review of the plans for discrimination, but we are finding that the 2015 plans are utilizing the same practices as they did in 2014, such as:

- Imposing arbitrary and unreasonable quantity limits on outpatient therapy that disproportionately impact patients, such as stroke survivors, who need multiple types of rehabilitative services to recover. For example, plans in Idaho limit coverage for physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) services to 20 total visits annually. Similarly, plans in Georgia and Mississippi are imposing a 20 visit annual limit for PT and OT combined and a 20 visit limit for SLP. For a stroke patient who is likely to need all three types of outpatient therapy, this limit translates into only about 2 weeks of outpatient rehabilitation. It is most unlikely that most stroke patients can learn how to walk or talk again with such limited coverage.

- Likewise, some plans are also imposing limits on cardiac rehabilitation that are not sufficient based on the medical evidence. Under the ACC/AHA guidelines, a full course of cardiac rehabilitation is generally 36 sessions over 12 weeks. Research has shown that participating in CR can reduce cardiac mortality by as much as 31 percent and it has also proven beneficial in preventing a second heart attack. Unfortunately, however, contrary to evidence-based medical guidelines, we have seen plans that are imposing inadequate and arbitrary visit limits. For example, a silver plan in Nebraska has an 18-visit limit for CR, which is half the number recommended by evidence-based guidelines.

- Some plans are imposing very high co-pays or co-insurance on specific services more likely to be used by patients with disabling medical conditions, effectively discouraging them from enrolling in those plans or accessing those services. For instance, a silver plan in Tennessee charges a 50 percent coinsurance per outpatient therapy visit. For a patient who has a heart attack or bypass surgery and who needs cardiac rehabilitation to help prevent another cardiac event, his or her out-of-pocket costs for cardiac rehab would likely be $2,000 or more for the amount of cardiac rehab recommended by evidence-based medical guidelines. Many stroke patients would also have high out-of-pocket costs for the therapy they need to learn to walk, talk, and function again.

- Some plans are charging a high co-insurance for prescription medications. Co-insurance as high as 40 or 50 percent put access to lifesaving medications out of reach for many people, particularly if they don't have other options for medications available on a lower formulary tier. We've also seen a number of 2015 plans that appear to violate the provision of the ACA requiring that plans charge consumers in-network cost-sharing for out-of-network emergency services. For example, a plan in Idaho is charging 30 percent coinsurance for in-network emergency room services but 50 percent coinsurance for out-of-network emergency room services. Another plan in South Carolina charges a $300 co-

pay then 50 percent coinsurance for "facility charges" for emergency room services in-network and out-of-network, but when the hospital is out-of-network, it also charges 100 percent coinsurance for all other emergency room services other than the facility fee.

It is critically important that HHS and other regulators begin enforcing the ACA non-discrimination provisions. HHS should also issue regulations that further define practices that constitute discrimination. For example, HHS should make it clear in regulation that limits must be grounded in medical evidence and should disapprove plans that include arbitrary limits. HHS could also require plans that impose limits to have an "exceptions process" that enables enrollees to access medically-necessary care that exceeds the limits, as exists in Medicare for beneficiaries who need more outpatient therapy than its caps allow. When reviewing plan cost-sharing requirements, HHS should evaluate whether high cost-sharing rates for specific categories of services, such as rehabilitation and habilitation, are likely to discourage enrollment of those with disabilities or chronic health needs and are therefore discriminatory.

Cost-Sharing Requirements (§156.130)

We applaud the clarification that non-calendar-year plans that are subject to maximum out-of-pocket limits are not permitted to reset the plan's annual limitation on cost sharing at the end of the calendar year, given that the end of the calendar year is not the end of the plan year. This change will ensure that enrollees' out-of-pocket spending for eligible expenses accrue toward one annual limit per plan year, as was intended under the law.

We also support HHS's proposed technical correction that makes it clear that issuers have the option to count the cost sharing for out-of network services towards the annual limitation on cost sharing, but are not required to do so. While we believe that plans should be required to count out-of-pocket spending for essential health benefits towards the annual limit, at the very least issuers should have the flexibility to count them if they choose to do so. We also encourage HHS to take another step in the right direction by requiring plans to count such spending toward the maximum out-of-pocket limit in two instances:

- When emergency services are received out-of-network. Under current regulations, issuers are only required to count out-of-network emergency services toward the maximum out-of-pocket limit if the out-of-pocket maximum applies generally to out-of-network benefits. However, such a policy is inconsistent with the intent of the ACA to protect consumers who must get emergency care at an out-of-network hospital, in circumstances that are often beyond their control.

- When enrollees access out-of-network services at the authorization of their plan, such as through single-case agreements, because the plan does not have a network provider of the required specialty or subspecialty with the professional training, expertise and experience to treat or provide health care services for the condition or disease or an in-network provider is not available without unreasonable delay. Single-case agreements are often used for children born with congenital heart disease who require specialized interventions that are only available in a very few medical centers across the

country. Accessing this care can greatly improve their chance of survival, but often their survival comes at a terrible financial cost to their parents. Counting the out-of-network cost-sharing toward the maximum out-of-pocket limit would help to alleviate this cost.

Transparency in Coverage (§156.220)

HHS is seeking comments on the data elements to be collected, the format that should be used, and the timeframe or schedule for reporting in plain language by QHPs on the transparency information that is required under section 1311(e)(3) of the ACA. Among the data that QHPs are required to report and make public is information on the number of claims that are denied, information on cost-sharing and payments for out-of-network coverage; and data on enrollment and disenrollment. This overdue information can be very helpful to consumers when choosing a health plan, and we support HHS's plan to begin collecting and publicly displaying this information for the 2016 plan year. We make the following specific recommendations with respect to the information to be collected:

- With respect to data on the number of claims denied, HHS should require QHPs to submit the percentage of claims that are initially denied, as well as the percentage of denied claims that are eventually paid following internal and external review processes. Percentage information will be much more helpful to consumers than actual numbers of claims denied, which would be meaningless to most consumers without any context.

- With respect to the cost-sharing information required under this section of the ACA, we support requiring QHPs to permit individuals to learn the amount of cost-sharing that the individual would be responsible for paying with respect to a specific item or service. As we mentioned in our comments above, this information is particularly important for consumers when it comes to co-insurance since consumers have no way of knowing how a 30 percent co-insurance translates into actual dollars without knowing what the cost of the item or service is. Therefore, it is critical that consumers be notified about the right to obtain this information from their plan in a timely manner.

- It is important that consumers be able to access this information when shopping for a QHP. Therefore, we encourage HHS to display this information through healthcare.gov alongside the SBC, provider directory, and list of covered drugs, in addition to requiring plans to post it on their website.

Network Adequacy Standards (§156.230)

In order for health care to be truly available and affordable to Americans, consumers need three things: 1) affordable health insurance, 2) coverage for the essential benefits they might need, and 3) timely access to health care providers that can provide the covered care. The two top and, at times competing, priorities for consumers when choosing health care coverage are cost and the inclusion of the providers they need in their health plan's network. These priorities are at the crux of the issues related to network adequacy, and consumers recognize the need to balance these priorities. The bottom line is that health insurance coverage is meaningless if consumers cannot get the covered benefits promised to them. Therefore, the Association supports stronger

network adequacy standards for QHPs as well as other private health plans that use networks. The Association, through our Consumer Representative to the NAIC, has been very actively involved in the NAIC's efforts to update its network adequacy model law. While we, too, are awaiting the results of the NAIC's work, we hope and expect that NAIC will complete its revisions early next year and HHS will incorporate stronger network adequacy requirements for the 2017 plan year.

We support the proposed modifications to clarify that minimum network adequacy criteria apply to all QHPs that use a provider network and that only providers that are contracted as in-network can be counted for purposes of meeting network adequacy requirements. The vast majority of QHPs use a provider network, so it is our expectation that virtually all QHPs will be required to meet minimum network adequacy standards. When determining network adequacy for plans that use a tiered network, we urge HHS to further clarify that only providers in the lowest cost-sharing tier will be counted for network adequacy purposes. Given that using providers who are assigned to a higher cost-sharing tier can result in significantly more out-of-pocket costs, consumers should be able to access all covered benefits through providers in the lowest cost-sharing tier without unreasonable travel or delay.

We also applaud HHS's efforts in the preamble to this section to encourage continuity of care for new QHP enrollees by urging network QHP plans to allow new enrollees in the midst of an ongoing course of treatment to continue that treatment with their current providers, even if those providers are not in their new plan's network. These protections would be more meaningful to all QHP enrollees if they were QHP requirements, and we urge HHS to put them in place uniformly for all plans by codifying them in regulation. In addition, we recommend that the following associated protections be put in place:

- In instances where an enrollee is permitted to continue getting care from a former provider, the copayments, deductibles, or co-insurance the enrollee must pay for the former provider's services would be the same as the enrollee would pay if receiving care from an in-network provider. In addition, the former provider should not "balance bill" the enrollee.

- For each condition or service, the enrollee should receive coverage for the lesser of the course of treatment or 90 days. At the end of that time, the health plan may elect to reassess the need for continued treatment and authorize continued coverage of services from the former provider.

In addition, we believe that continuity of care requirements should be included in the rule not just for new enrollees in QHPs, but for enrollees in the midst of a course of treatment when their provider leaves their plan's network. Some states already have these types of continuity protections for insurance enrollees, and the NAIC Network Adequacy Model Review Subgroup is moving towards adding continuity of care requirements to its updated model law.

Regarding HHS's plans to continue to use the reasonable access standard adopted in the 2015 Letter to Issuers for 2016, we urge HHS to consider adding to its assessment of hospital network adequacy an assessment of whether plans that contract with hospitals to be in-network also include sufficient in-network physicians, such as emergency department doctors, anesthesiologists, radiologists, and hospitalists, at those

in-network hospitals. Analysis of data from Texas PPO plans by the Center for Public Policy Priorities found that for two of the largest insurers in the state, 48 percent and 56 percent of their in-network hospitals, respectively, had not a single in-network Emergency Department physician. One plan in particular also reported that 38 percent of their in-network hospitals had no in-network anesthesiologists and 31 percent had no in-network radiologists. This leaves consumers vulnerable to balance billing and the Association finds this unacceptable.

We also strongly support the new provider directory requirements of 156.230(b). Explicitly requiring QHP issuers' provider directories to be "up-to-date, accurate, and complete" is an important legal protection for consumers, and we support that the rule specifies that information on all current providers is to be accessible to the general public. It is also important that the rule codifies protections requiring directories to be available without consumers having to create or access accounts on issuer websites or having to enter policy numbers, and that consumers can easily discern which directories correspond to which specific health plans from a given issuer.

HHS should consider clarifying that QHP issuers must meet the requirements in 156.230(b) year-round and not only during open enrollment season. This is important as enrollees need access to provider directories to find new providers at all times during the year, and new enrollees join plans mid-year due to special enrollment opportunities and therefore many need to compare different plans' directories at various times during the year. This past year, certain insurers' provider directories were down for many months at a time mid-year, causing great challenges for enrollees and prospective enrollees alike. This must be prevented in the future.

The Association also supports the information that must be included in the directories, including "information on which providers are accepting new patients, the provider's location, contact information, specialty [and we would also add "subspecialty"], medical group, and any institutional affiliations." However, missing from this list is information about the tier to which the provider is assigned, if applicable. This information has very important cost-sharing implications for consumers in plans with tiered networks and should be readily accessible. In addition, we would also recommend inclusion of the following information: which languages other than English, if any, that providers speak; the provider's gender; any interpreter services or communication and language assistance services that are available at the provider's facilities, and information about how enrollees can obtain such services; the physical accessibility of the provider's facilities; and specific descriptions of any available telemedicine services.

The preamble to section 156.230(b) states, "we propose that a QHP issuer must update the directory information at least once a month." We support this standard and recommend that the final regulation be modified to require that directory information be updated as frequently as required under guidance from HHS.

Given that most plans do update their directories frequently based on the information they receive from providers, but very severe provider directory inaccuracies persist, we encourage HHS to put in place additional measures to address this problem. Inaccurate directories mask issues of inadequate networks and make it impossible for consumers to identify plans that meet their needs when shopping and find providers when it is time for them to obtain care. While standards that require plans to conduct timely directory

updates are important for directory accuracy, they simply are not sufficient. The types of requirements that HHS could also institute to help achieve greater directory accuracy include:

- A requirement that all plans prominently list in their directories an email address or phone number for members of the public to directly notify the plan when provider directory information is inaccurate and a requirement that plans be accountable for investigating these reports and modifying directories accordingly in response.

- A requirement that plans internally audit their directories and modify directories accordingly based on audit findings.

- A requirement that plans contact providers listed as in-network who have not submitted claims within the past six months to determine whether the provider still intends to be in network and modify their directories accordingly.

- A requirement that plans honor provider directory information. If a consumer relies on materially inaccurate information from a directory indicating that a provider is in-network and receives care from that provider, the plan should be required to hold the consumer harmless and charge the consumer only in-network cost-sharing for the care.

Finally, we support the concept of requiring issuers to make their provider network information publicly available in machine-readable files and formats as specified by HHS. We believe this would be beneficial for creating different ways that consumers could access provider information, and hopefully could also catalyze increased accuracy of provider directories as more entities review directory information and make it publicly accessible. We also support the submission of this type of information directly to HHS and hope that HHS can eventually create integrated provider directories for the FFM. Integrated, searchable directories could potentially be more accurate than existing directories if they allowed integrated updates. For example, if a provider retired, the provider could inform the marketplace that he or she was no longer practicing, and the provider could be removed this provider from all plans' directories simultaneously, instead of having to communicate with multiple issuers' and wait for each of those issuers to remove the provider's information from their directories.

Plan Variations (§156.420)

We support the proposed amendment to require QHP issuers to provide SBCs that accurately represent plan cost-sharing variations. Consumers shopping for coverage for 2014 who had been determined eligible for cost-sharing assistance were often understandably confused that the SBC available for their plan did not accurately reflect their deductible and other cost-sharing. We note that many issuers have developed SBCs for plan variations for the 2015 plan year, so this should not be an unduly burdensome new requirement.

Quality Improvement Strategy (§156.1130)

Although the United States has been successful in reducing death rates for heart disease and stroke—the No. 1 and No. 4 leading causes of death in the United States—much work remains to address these leading causes of death and disability. Among other issues, the fragmentation of services and the lack of coordination of care for people with chronic conditions are a major cause for concern. The Association believes that changes to the fundamental way in which care is delivered, including how the patient is incorporated into the care delivery and decision-making process and the way in which (s)he interacts with the care provider, is crucial to driving significant improvements in the quality and efficiency of care and patients' access to it.

As part of its commitment to improving patient care for CVD and stroke, the Association has developed a number of quality improvement programs in order to raise the bar on quality patient care. Our quality improvement suite of programs is based on the idea that providers have access to clinical care guidelines and patient information at the point of care and receive regular feedback comparing their performance to national benchmarks to improve the quality of the care they deliver. For example, our inpatient quality improvement program, Get With The Guidelines (GWTG), is the premier hospital-based quality improvement program for the AHA/ASA. It empowers healthcare providers and their teams to constantly treat heart and stroke patients according to the most up-to-date treatment guidelines. The goal of GWTG is simple: to help hospitals save more lives by optimizing care for coronary artery disease, heart failure and stroke patients. Likewise, the program helps maximize continuing quality of life for those patients and their families through improved outcomes and a reduction in recurring events. Simply put, the AHA/ASA is committed to quality improvement and applauds HHS for outlining the parameters for quality improvement strategies to be deployed by QHPs.

We would like to take this opportunity to stress the important role QHPs play in helping providers identify tools that can help improve the quality of care for their patients. The Association appreciates the Department's effort to align the QHP quality improvement activities to the National Quality Strategy (NQS) and the Center for Medicare and Medicaid Services Quality Strategy. It is imperative for HHS to align and leverage all quality improvement activities as required by the ACA, including the quality reporting systems, to ensure that quality activities are appropriately incentivized and a priority to QHPs. Although we support the framework set out in the NQS and applaud HHS for requiring QHPs to develop quality improvement strategies that do address the pillars outlined in the NQS, we believe that the priorities set out in the NQS are not detailed enough and do not differentiate from quality improvement activities that are already underway by QHPs. It is important for HHS to set the standard high in order to drive QHPs to develop ambitious plans with strong implementation strategies that will result in quality improvement strategies that will incentivize the delivery of high-quality, evidence-based care. In order to close the quality gap, QHPs will have to encourage the adherence to clinical practice guidelines and measures; the use of clinical data registries; robust data linkage; and care coordination across the care continuum with an incentive for better transitions of care.

Issuer Use of Premium Revenue: Reporting and Rebate Requirements (Part 158)

Finally, we support the proposed amendments to the medical loss ratio (MLR) reporting and rebate requirements, making it clear that federal and state employment taxes should not be excluded from premium in the MLR reporting and rebate calculations. This change is consistent with our understanding of the intent of Congress with respect to the treatment of federal taxes, as expressed in a 2010 letter from the chairs of each of the committees of the House and Senate that had jurisdiction over the ACA. More importantly, the change is also beneficial to consumers, as evidenced by the estimate that this clarification could result in additional rebate payments to consumers of approximately $35 million.

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Thank you again for the opportunity to share our comments on these issues related to special enrollment periods, provision of essential health benefits, network adequacy, and other important topics. If you have any questions, please feel free to contact Stephanie Mohl, Senior Government Relations Advisor, at Stephanie.Mohl@heart.org or 202-785-7909.

Sincerely,

Elliott M. Antman, MD, FAHA
President