November 27, 2017

The Honorable Eric D. Hargan  
Acting Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

RE: Docket No. CMS-9930-P

Dear Acting Secretary Hargan:

On behalf of the American Heart Association (AHA) and the American Stroke Association (ASA), we appreciate this opportunity to submit comments on the Centers for Medicare and Medicaid Services’ (CMS) proposed rule, “Notice of Benefit and Payment Parameters for 2019”, (NBPP).

As the nation’s oldest and largest voluntary organization dedicated to building healthier lives free from heart disease and stroke, we would like to express our significant concerns with several policies included in the proposed rule. Our nonprofit and nonpartisan organization represents over 100 million patients with cardiovascular disease (CVD) and includes over 30 million volunteers and supporters committed to our goal of improving the cardiovascular health of all Americans. AHA has worked diligently for many years to support and advance strong public health policies in addition to providing critical tools and information to providers, patients, and families to prevent and treat these deadly diseases.

The connection between health insurance and health outcomes is clear and well documented. Americans with CVD risk factors who lack health insurance, or are underinsured, have higher mortality rates\(^1\) and poorer blood pressure control than their insured counterparts.\(^2\) Further, uninsured stroke patients suffer from greater neurological impairments.

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\(^2\) McWilliams JM, Zaslavsky AM, Meara E, Ayanian JZ. Health insurance coverage and mortality among the near-elderly. Health Affairs 2004; 23(4): 223-233.

"Building healthier lives, free of cardiovascular diseases and stroke." *life is why*, *es por la vida*, 全为生命
longer hospital stays\(^3\), and higher risk of death than similar patients covered by health insurance. \(^4\) Cardiovascular disease is also costly and burdensome to patients, their families and communities, and our system of care.

We have long advocated for all Americans to have access to affordable, quality health insurance coverage and care, with a focus on the prevention and elimination of disparities based on race, gender, and geography.\(^5\) Throughout implementation of the Affordable Care Act (ACA), we remained focused on access to affordable and adequate health insurance coverage. Since then, the association has worked to ensure that any health care proposal issued by Congress or the Administration to adjust the law was measured against a set of patient-focused principles.\(^6\) They include:

- **Health Insurance Must be Affordable** – Affordable plans ensure patients are able to access needed care in a timely manner from an experienced provider without undue financial burden. Affordable coverage includes reasonable premiums and cost sharing (such as deductibles, copays and coinsurance) and limits on out-of-pocket expenses. Adequate financial assistance must be available for low-income Americans. Individuals with preexisting conditions should not be subject to increased premium costs based on their disease or health status.

- **Health Insurance Must be Accessible** – All people, regardless of employment status or geographic location, should be able to gain coverage without waiting periods through adequate open and special enrollment periods. Patient protections in current law should be retained, including prohibitions on preexisting condition exclusions, annual and lifetime limits, insurance policy rescissions, gender pricing and excessive premiums for older adults. Children should be allowed to remain on their parents' health plans until age 26 and coverage through Medicare and Medicaid should not be jeopardized through excessive cost-shifting, funding cuts, per capita caps, or block granting.

- **Health Insurance Must be Adequate and Understandable** – All plans should be required to cover a full range of needed health benefits with a comprehensive and stable network of providers and plan features. Guaranteed access to and prioritization of preventive services without cost-sharing should be preserved. Information regarding costs and coverage must be available, transparent, and understandable to the consumer prior to purchasing a plan.

We are deeply concerned that many of the policies and changes included in the proposed rule fail to measure up to our three core principles. Overall, CMS is proposing


\(^4\) McWilliams JM, Meara E, Zaslavsky AM, Ayanian JZ. Health of previously uninsured adults after acquiring Medicare coverage. JAMA. 2007; 298:2886–2894.


to eliminate a panoply of standards that have served to protect patients and consumers since the ACA’s implementation, including those related to benefit structure, cost protections, and oversight. In this letter, we focus our comments on the issues that we believe are particularly concerning for those who have, or are at risk of, cardiovascular disease and stroke.

**Part 154 – Health insurance Issuer Rate Increases: Disclosure and Review Requirements**

**Rate Review**

In the rule, CMS proposes to increase the rate review threshold from 10 percent to 15 percent. We believe such a modification would unduly hurt healthcare consumers while providing minimal and unnecessary regulatory relief to insurers.

Historically, the rate setting process for health insurance has lacked transparency and recourse for consumers affected by exorbitant rate hikes. The introduction of rate review standards at the national level has proven to be an effective tool in reducing high healthcare costs imposed on consumers. In 2015 alone, rate review saved approximately 6.5 million consumers an estimated $1.5 billion in the individual and small group markets combined. Rate review also decreased the number of requested double-digit rate increases by almost 25 percent.

Increasing the rate review threshold to 15 percent would significantly hinder the ability of state insurance departments to protect consumers against potentially inappropriate rate increases. This policy change would likely lead to more double-digit rate increase requests and higher premiums for consumers. Audits have been a critical component of ensuring price transparency within our healthcare system and oversight within appropriate margins is essential to ensuring health care is affordable for patients and consumers. In 2015, the average rate increases in the individual market and small group markets were well under the current 10 percent threshold (6.9 percent and 4.3 percent, respectively). Increasing the threshold to 15 percent would provide no incentive to moderate these increases by only identifying those with the most egregious rate hikes.

Changes to the rate review threshold are also problematic for the young. Often viewed as a problem of adults, cardiovascular disease also exacts a terrible toll on children and young adults. Congenital cardiovascular defects, also known as congenital heart defects (CHD), are the most common birth defect in the U.S. Fortunately, due to significant research advances, most survive to adulthood.

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8 Ibid.
9 Ibid.
However, as these diseases progress throughout their lives, young adults with CHD face enormous barriers to effective health care, particularly when they are no longer covered by their parents’ health plans. It is critical that they have access to care through the exchanges, their employers or through their educational institutions.

For this reason, we also strongly oppose the exclusion of student health coverage from rate review. Access to adequate care is critical to managing chronic disease over time. For young adults with CHD and many other young people, student health insurance is a crucial tool to ensure they can effectively manage their disease and prevent more serious downstream effects. Because of this, we see no reasonable argument for allowing rate increases to occur in this area unchallenged.

The cost of health insurance is a serious burden for people living with or at risk of chronic illness such as CVD. For this reason, AHA opposes raising the rate review threshold and allowing higher rate increases to go unchecked and urges CMS to continue to include student health insurance under current standards in the rate review process.

**Part 155 – Exchange Establishment Standards and Other Related Standards under the Affordable Care Act**

**Standardized Options**
CMS is soliciting comments on the elimination of standardized plans and differential displays. Though we agree that innovative plans could, in theory, benefit Marketplace consumers, we are concerned that this proposal may, in fact, increase confusion, particularly among those receiving specialized care like individuals with CVD, who rely on standardized options to allow for a more straightforward comparison of their coverage options.

CMS proposes to encourage innovation by eliminating standardized plan options altogether. Under current law, issuers were never required to offer standardized plans, but rather had been given the option of offering standardized options, as well as non-standardized plans. As a result, consumers who were interested in an apples-to-apples comparison could more easily compare plans that fit the standardized framework.

Removing consumers’ ability to compare standardized plans – offered at the option of issuers, not by government mandate – could make choosing the appropriate plan more difficult. We therefore strongly oppose this change and urge CMS to maintain the issuers’ option of offering standardized as well as non-standardized plans.

**Navigator Program**
We are deeply concerned about CMS’s proposed policy change that would scale back the Navigator program. Navigators offer a critically important and unparalleled benefit for enrollees. Navigators help people who need health insurance enroll in marketplace plans while also educating consumers about their coverage options, including Medicaid and Medicare. Marketing, education and outreach conducted by Navigators are essential to promoting a healthier, balanced risk pool, which benefits the entire market by helping
bring down the cost of insurance and stabilizing the market.\textsuperscript{12} Patients and their families, including those with CVD, rely on Navigators as a resource to finding and attaining adequate and affordable health care coverage through the most appropriate program. Reducing or scaling back support for these services poses a serious threat to the short- and long-term wellbeing of patients. Navigators are a critical bridge to accessing and understanding health care information and coverage for patients and consumers.

Typically, Navigators are approachable, trusted members of their communities who know the challenges and understand the culture of those they serve. We are deeply concerned that reducing the number of Navigator entities, while also eliminating the requirement to include consumer-focused and in-state entities, could result in a significant number of consumers left without reliable support to effectively manage the enrollment process.

CMS suggests there is a need for greater flexibility in the Navigator grant award process. While we share CMS’s goal of ensuring that states select the strongest Navigator grantees, it is unclear what problem CMS is attempting to solve by removing the requirements that at least one entity in each exchange be a community and consumer-focused nonprofit group, and that Navigators have a physical presence in the state.

Instead, the agency’s proposed changes seem to further open the door to priorities not in line with the best interests of the consumers and community. Removing the requirement that Navigators maintain a physical presence in the region would allow states to select Navigator entities with weaker community ties and could result in consumers losing access to the in-person assistance on which they rely. This risk is not justified by any evidence provided by CMS that the current Navigator grant structure has created problems that warrant its restructuring. We therefore oppose both changes.

These proposed changes are of greater concern in light of the multiple actions the Administration has taken to restrict patient access to coverage including, limiting open enrollment and special enrollment periods, reducing outreach and enrollment funding and discontinuing cost sharing reduction (CSR) payments. Moving away from on-the-ground, community-based education and enrollment programs will likely result in additional barriers to coverage. If CMS is concerned about meaningful access to Navigators, it should immediately reverse the major funding cuts the Administration has made to Navigator programs nationally.\textsuperscript{13}

\textbf{Income Inconsistencies}

AHA is concerned about the proposed income verification procedures outlined in the NBPP and their impact on consumers, especially those with low incomes. CMS proposes to use Internal Revenue Service (IRS) and Social Security Administration (SSA) data to verify that individuals with annual incomes below the federal poverty level


(FPL) do not report incomes greater than 100 percent FPL in order to gain eligibility for premium assistance.

While the stated purpose of this proposal is to ensure program integrity, the realized effect would likely be to hurt people whose incomes vacillate above and below the poverty level based on inconsistent employment and/or income.

It is also unclear what, if any, pathway CMS would use to remediate denied claims, especially those that are made in error or from inaccurate or incorrect information. Leaving patients, especially those with serious or chronic diseases, without access to care could have serious negative impacts on their health. Individuals with incomes hovering at or around FPL should not be punished for obtaining health insurance simply because they lack predictable incomes and live in states that have not expanded Medicaid.14

CMS has not provided any supporting data to validate its claim that the premium assistance program lacks integrity. It is unclear how often those under 100 percent FPL receive premium assistance due to overestimation, how much this premium assistance costs—both as an average and in aggregate—and why CMS has decided to focus on this specific policy area at this time. Furthermore, the change runs counter to CMS’s stated overarching goals, and increases the regulatory and administrative burden on states.

Third-party Auditing
CMS proposes to adjust the auditing approach it implemented in the 2018 Payment Notice by canceling the requirement for CMS review of third-party auditors for direct enrollment entities, such as agents, brokers, and insurers. Though we appreciate the desire to limit duplicative efforts, we do not believe that relying on accreditation from an external entity is sufficiently comparable to direct government oversight. We are concerned about the trend apparent here and in the Navigator requirements towards the diminishment of meaningful oversight of consumer-facing services, particularly those that have access to patient information as part of the enrollment process. Monitoring compliance with federal standards after auditors have been selected disregards the preventative role of oversight and corrective actions involving patient information are much more difficult after the fact. Pushing it too far downstream invites greater potential for abuse.

Special Enrollment Periods
Special Enrollment Periods (SEPs) are a key part of the mission to provide consumers with affordable and accessible health insurance at every stage of their lives. As individual and familial circumstances change throughout the year, it is important that consumers are able to enroll in or switch into plans of their choice during times of change or transition. Such continuity is particularly important for people with, or at risk of CVD, who often need to maintain medical visits because of serious or chronic health events or medications.

Their ability to access care through SEPs helps stabilize the marketplace by ensuring people maintain coverage that is appropriate for their needs. Therefore, we are concerned about CMS’s ongoing efforts to limit the availability and accessibility of SEP opportunities for consumers. Without adequate opportunities to seek and achieve medical coverage, patients, especially those with CVD, can suffer serious primary or secondary cardiac events with adverse implications on both their own physical health and the fiscal health of the entities that provide emergency care.

We do, however, support the proposed changes that would allow women who lose access to pregnancy-related CHIP coverage to qualify for a 60-day SEP, because it would provide a route to coverage for women who might otherwise be left uninsured. Women experience profound changes in their circulatory system during pregnancy, delivery, and the postpartum period, making it particularly important for them to be able to afford heart healthcare during this period.\(^{15}\) However, pregnancy is only one example of a life event that impacts a person’s health, and it underscores the need for all people to be able to gain and retain access to coverage.

While we continue to oppose continuous coverage requirements as a pre-requisite for SEP availability, we support CMS’ proposal to exempt individuals in bare counties from this policy, as it would protect consumers should these circumstances arise. AHA is pleased that in plan year 2018, every county in the United States has at least one issuer participating in the marketplace. We strongly encourage HHS to continue to work with issuers to ensure participation so that this exemption is not necessary in future plan years.

**Part 156 – Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges**

**Essential Health Benefits**

AHA strongly opposes the proposal to weaken Essential Health Benefit (EHB) requirements. We view defining the EHB package as among the most important regulatory tasks required by the ACA, and have previously recommended that HHS define a national, evidence-based EHB package based on recommendations from the Institute of Medicine.\(^{16}\) The policies included in the proposed rule move in the opposite direction.

Under the proposed NBPP, states would have more flexibility to select an EHB-benchmark plan. A state could:

- maintain its current EHB-benchmark plan;
- choose another state’s EHB-benchmark plan, either in part or in whole;
- choose elements from EHB-benchmarks in multiple states, or;
- select an entirely new EHB-benchmark plan so long as it is comparable to a “typical employer plan.”

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AHA is concerned that this flexibility would potentially allow states to design benchmark plans that offer not just less generous coverage, but the least generous coverage of each of the ten EHBs available across the country, or to develop new EHBs that are even sparser. Under the proposed rule, other states could then duplicate these benchmark plans and subject even more Americans to limited or skimpy EHB coverage.

AHA is particularly concerned about the impact this proposal could have on drug formularies. Plan formularies are probably the easiest benefit category to “cut and paste” from one plan to another, allowing states to easily select a less generous benefit if they so choose. It is important that consumers have adequate access to the prescription drugs they need to prevent and treat diseases, like CVD, and AHA opposes any measure that would jeopardize this access. We are similarly concerned about the mention of a potential future federal formulary, which, depending on implementation, could reduce drug coverage in all states.

The proposal would also allow issuers to substitute across, rather than only within, EHB categories. Even in a state that chooses to maintain a robust EHB benchmark, issuers could weaken coverage for consumers.

While all consumers could be negatively impacted by this EHB benchmark plan design, it is especially harmful to healthcare consumers with higher costs and needs, including individuals with CVD. Decreasing the value any one of the EHB categories could affect access to ambulatory care, emergency care, or other crucial services that patients need in order to live healthy and productive lives.

Compounding our concerns is the fact that prohibitions on annual and lifetime caps only apply to EHB benefits. As the definition of EHB contracts, this protection becomes less meaningful to consumers, who once again may become vulnerable to catastrophic medical losses. In 2007 alone, more than 60 percent of all bankruptcies were a result of serious illness and medical bills – more than a quarter of these bankruptcies were a result of CVD. In a survey commissioned by the AHA, one in five (21 percent) of respondents said they “frequently” put off care because of costs involved, and among those with CVD, 51 percent said they occasionally put off care because of costs. Heart transplants and surgeries for the approximately 40,000 babies born with heart defects each year are clear-cut examples of how caps on coverage can quickly be reached. The changes to the EHB structure, and therefore lifetime and annual caps, included in the proposed rule would also impact large group coverage as well.

The AHA strongly opposes the proposed changes to EHB because of its potentially devastating impacts on the health and wellbeing of the CVD population.

18 Perry Undem. American Heart Association-commissioned National Survey, Conducted March 3-13, 2017
Qualified Health Plan (QHP) Minimum Certification Standards

AHA agrees with CMS that states should play a role in the structure and management of their Exchanges. However, we believe that transferring oversight of QHP standards and certification to the states is only appropriate when states have the expertise and capacity to ensure that minimum federal network adequacy standards are met. As CMS in fact acknowledges, some states may not have the authority or means to conduct network adequacy reviews. We oppose CMS’s ongoing effort to rid itself of oversight responsibility for this crucial consumer standard.

AHA is also concerned about keeping the Essential Community Provider (ECP) participation level at 20 percent, and we recommend returning to the previous 30 percent requirement. ECPs, such as Federally Qualified Health Centers, are a key source of chronic disease screenings, disease maintenance, and care. One in thirteen people seek treatment and care through an FQHC each year. It is imperative that networks contain enough ECPs so that consumers, particularly those with CVD, have sufficient access to important preventive and treatment services. CMS has not presented evidence that a higher standard poses a significant challenge for issuers; however, this provision has substantial ability to restrict access to care for patients.

Finally, CMS has proposed removing the meaningful difference standard, ostensibly to lessen administrative burden on the issuers and potentially increase the number of QHPs offered on the exchange. AHA opposes the elimination of this standard. Increased choice of QHPs on the marketplace is only helpful if consumers can understand the differences between plans. The meaningful difference standard currently ensures that plans marketed on the exchange are distinct enough that “a reasonable consumer would be able to identify one or more material differences among five key characteristics between the plan and other plans to be offered by the same issuer.” Understanding available options, and what they mean in terms of care, is critical for all patients including those with CVD. Eliminating this requirement would render superfluous any increase in QHP availability by making the marketplace more confusing and overwhelming for average consumers. Additional barriers to understanding care options are unacceptable and AHA strongly opposes this proposal.

HSAs

CMS states in the preamble that it “would like to encourage issuers to offer High Deductible Health Plans (HDHPs) that can be paired with an HSA as a cost-effective option for enrollees” and expresses interest in “exploring how to use plan display options on HealthCare.gov to promote the availability of HDHPs to applicants.” While we understand the benefits of promoting plan innovation, it is important that marketplaces do not obscure the potential risks of HSA-eligible HDHPs. In particular, we are concerned about the numerous demographics of people for whom HDHPs are potentially inappropriate, including patients with chronic disease - including CVD - and those without the financial resources to afford significant out-of-pocket medical costs.

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We agree that HSA-eligible HDHPs, particularly those with expanded pre-deductible coverage, can offer value to certain individuals when paired with an HSA. However, these individuals tend to be healthier and wealthier and rely in part on third-party (i.e., employer) contributions to fund their HSAs. Such individuals are atypical in the exchanges—and though HSAs are appealing for their lower monthly premiums, plans’ limited pre-deductible coverage may pose substantial risk to those with significant medical need.\textsuperscript{24,25} In addition, many enrollees in HSA-eligible plans do not necessarily have an HSA or sufficient funds to adequately finance an HSA to fund their pre-deductible care, and therefore face the burden of a high deductible without the HSA’s tax benefits.

Faced with the potentially significant out-of-pocket expenses of their care, studies have shown that people enrolled in high deductible plans put off necessary treatment for chronic conditions or fall out of care,\textsuperscript{26} especially when cost is a major concern.\textsuperscript{27} Many eventually need more expensive emergency care as a result,\textsuperscript{28} which works against efforts to contain costs and promote market stabilization.

For these reasons, HDHP enrollment should not be driven by a presumption that HSA-eligible plans are inherently cost-effective. Rather, consumers should be clearly informed about both the risks and benefits of HSA-eligible plans, as well as how to use them in combination with an HSA, and how to determine if they are the right choice for that consumer. Those who stand to benefit from HSA-eligible HDHPs would see that value reflected in the information offered to them. We strongly believe that any strategy to encourage enrollment in a certain health plan must include clear consumer education to help the consumer meaningfully discern the value of that plan.

\section*{Part 158 – Issuer Use of Premium Revenue: Reporting and Rebate Requirements}

\textbf{Medical Loss Ratio}

AHA opposes weakening Medical Loss Ratio (MLR) requirements for insurers. Most insurers do not have problems meeting MLR requirements,\textsuperscript{29} and have managed to reduce overhead costs and spend more of beneficiaries’ premiums on care. In 2011,

\begin{itemize}
  \item \textsuperscript{27} Perry Undem. American Heart Association-commissioned National Survey, Conducted March 3-13, 2017
\end{itemize}
insurers paid beneficiaries over $1 billion in rebates, but rebate payments have gradually declined; in 2016, rebate payments were only $397 million.30

Despite evidence that current MLR requirements have reduced overhead spending by insurers without undue burden, CMS proposes loosening the requirements for insurers. First, the proposed regulation seeks comment on the exclusion of employment taxes from premiums in MLR calculations – lowering the MLR denominator and therefore making it easier for issuers to meet. AHA opposes this measure because it would allow issuers to spend less on care and still meet the threshold. The proposed regulation also asks for input on an automatic addition of 0.8 percent earned premium for “quality improvement expenses” in the MLR calculation. AHA opposes granting insurers an automatic premium; issuers should only be rewarded for actual investment in quality improvement activities, and would in fact lose the incentive to do so if awarded this premium automatically.

Most concerning, the proposed rule suggests a system of state-by-state MLR adjustments. Under this proposal, states could petition HHS to lower MLR requirements if doing so would stabilize the state’s marketplace. While such a system was in place during the first three years of implementation of the current MLR requirement, fewer adjustments have been required or requested in recent years.31 Allowing states to once again request adjustments to MLR requirements would do little to stabilize markets, but would impact consumers’ ability to ensure that their premium dollars are being primarily spent on the care that they receive.

CMS also proposes to lower the requirements for states to request MLR adjustments. Currently, states must provide CMS with “the State MLR standard and formula for assessing compliance (§158.321(a)), its market withdrawal requirements (§158.321(b)), and the mechanisms available to the State to provide consumers with options for alternate coverage (§158.321(c)).” CMS acknowledges that “[t]his information is used to determine what a State is able to do to mitigate instability in its individual market without an adjustment to the MLR standard.” By eliminating such requirements for a state’s MLR adjustment petition, CMS would undermine its own ability to determine if an MLR adjustment is appropriate and how adjusting the MLR would impact consumers. While AHA opposes weakening the MLR requirements in general, should CMS insist on moving forward with this proposal despite its potential to harm consumers, we strongly oppose requiring less information of states as they make a case to support MLR adjustments.

Conclusion

AHA is committed to the continued implementation of federal health policy in a way that reflects our principles of consumer access to affordable, understandable and adequate healthcare. The loosening of oversight and consumer protection standards included in CMS’s proposed rule could jeopardize access to meaningful coverage for vulnerable patients, including those with cardiovascular disease in a number of ways. We are concerned that this rule, combined with the series of actions taken by the Administration, including decreased education and outreach funding, non-payment of CSRs, and a

30 ibid
31 ibid
shortened open enrollment period among others, continues to erode consumers’ ability to understand their coverage options, gain coverage, and improve their health. We are also concerned that CMS has only provided a 30-day comment period for this rule, even though it will have serious implications for consumers.

We urge you to accept our recommendations about the impact of the proposed rule on the ability for CVD patients to seek adequate, understandable and affordable care seriously, and revise the rule appropriately.

We look forward to working with CMS and other stakeholders to promote quality, affordable care. If you have any questions, please contact Katie Berge, AHA Government Relations Manager, at katie.berge@heart.org or 202-785-7909.

Sincerely,

Sue Nelson
Vice President of Federal Affairs