



July 2, 2019

The Honorable Alex M. Azar II  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SE  
Washington, DC 20201

The Honorable Seema Verma  
Administrator  
Center for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

The Honorable David J. Kautter  
Assistant Secretary (Tax Policy)  
Department of the Treasury  
1500 Pennsylvania Avenue, NW  
Washington, DC 20220

**Re: Request for Information Regarding State Relief and Empowerment Waivers (CMS 9936-NC2)**

Dear Secretary Azar, Administrator Verma and Assistant Secretary Kautter:

Thank you for the opportunity to submit comments on the request for information (RFI) regarding ideas for innovative programs and waiver concepts that states could consider in developing a 1332 waiver plan.

The undersigned organizations represent millions of patients and consumers facing serious, acute and chronic health conditions across the country. We have a unique perspective on what individuals and families need to prevent disease, cure illness and manage chronic health conditions. Our diversity enables us to draw upon a wealth of knowledge and expertise that can be an invaluable resource in this discussion. We urge the Department of Health and Human Services (HHS), the Centers for Medicare and

Medicaid Services (CMS) and the Department of Treasury (Treasury) to utilize the collective insight and experience our patients and organizations offer in response to the request for information.

In March of 2017, our organizations agreed upon three overarching principles<sup>1</sup> to guide any work to reform and improve the nation's healthcare system. These principles state that: (1) healthcare should be accessible, meaning that coverage should be easy to understand and not pose a barrier to care; (2) healthcare should be affordable, enabling patients to access the treatments they need to live healthy and productive lives; and (3) healthcare must be adequate, meaning healthcare coverage should cover treatments patients need, including all the services in the essential health benefit (EHB) package.

Section 1332 waivers allow states to waive specified provisions of the Affordable Care Act (ACA), provided the state's waiver plan meets four statutory guardrails: coverage must be as affordable as it would be without the waiver; coverage must be as comprehensive as it would be without the waiver; a comparable number of people must be covered under the waiver as would be without it; and the waiver must not add to the federal deficit. In 2018, HHS and Treasury issued new State Relief and Empowerment Waivers guidance, followed by a Section 1332 State Relief and Empowerment Waiver Concepts Discussion Paper, that supersedes guidance from 2015 for states on how to design these waivers. Unfortunately, the new guidance neither adheres to our organizations' sound principles for reforming and improving the nation's healthcare system nor the federal law requirements it purports to interpret. As many of our organizations wrote in detailed comments submitted to HHS and Treasury in December 2018 (see Attachment A), the policies that states could pursue under the new guidance would significantly undermine quality and affordable healthcare for patients with pre-existing conditions. The guidance will make it easier for states to use federal taxpayer dollars to promote sub-standard plans that do not provide comprehensive and affordable coverage. And it tips the scales in favor of insurance products that are inadequate to meet the needs of the millions of patients and consumers our organizations represent. We reiterate our request that HHS and Treasury rescind this guidance.

Additionally, to ensure that 1332 waivers do not jeopardize accessible, affordable and adequate healthcare coverage for patients, we urge the Administration to reconsider some of the principles also outlined in the October 2018 guidance. The RFI notes that the Secretaries will "consider favorably" applications from states that meet some or all of the Departments' five principles. However, some of these principles may limit states' ability to submit innovative programs and waiver concepts. For example, under the principle to provide increased access to affordable private market coverage, the guidance notes that states "should foster health coverage through competitive private market coverage, including Association Health Plans and short-term limited duration insurance plans, over public programs." This policy discourages states from pursuing a public option that provides comprehensive and affordable coverage while improving competition in the state marketplace.

Our organizations also encourage the Departments to continue to support 1332 waivers to implement reinsurance programs, a waiver concept that was included in the discussion paper released in 2018 and has been approved by the Departments both before and after the release of the October 2018 guidance. Reinsurance is an important tool to help stabilize health insurance markets. Reinsurance programs help insurance companies cover the claims of very high cost enrollees, which in turn helps make premiums more affordable for individuals buying insurance on the individual market. A recent analysis by Avalere of the seven states that have already created their own reinsurance programs through Section 1332 waivers found that these states reduced individual market premiums by an average of 19.9 percent in

their first year.<sup>2</sup> This helps patients with pre-existing conditions obtain affordable, comprehensive coverage.

Finally, our organizations encourage the Departments to make clear to states that any waiver applications must receive and incorporate feedback from stakeholders, including the patient community, prior to submission to CMS for approval. The ACA requires a state applying for a 1332 waiver to “enact a law . . . that provides for State actions under a waiver under [Section 1332], including the implementation of the State[']s [waiver] plan.” However, under the new guidance, a state can meet this requirement if it can point to (1) a law that provides general authority to enforce the ACA; and (2) more specific executive branch action (a regulation or executive order). This interpretation is at odds with the plain language of the ACA and removes an important opportunity for stakeholders to share feedback with state legislators and shape the waivers that states submit. Additionally, during the state public comment period on a draft waiver application, it is critical that stakeholders have access to all of the necessary application materials, including the economic and actuarial analyses of the waiver’s effects on coverage and costs, before being asked to provide feedback.

Thank you for the opportunity to provide comments. Our organizations once again urge you to rescind the October 2018 State Relief and Empowerment Waivers guidance and would be happy to work with you on waiver concepts that would ensure accessible, affordable and adequate coverage for patients with pre-existing conditions.

Sincerely,

American Cancer Society Cancer Action Network  
American Heart Association  
American Liver Foundation  
American Lung Association  
Arthritis Foundation  
Chronic Disease Coalition  
Cystic Fibrosis Foundation  
Epilepsy Foundation  
Hemophilia Federation of America  
Leukemia and Lymphoma Society  
March of Dimes  
Muscular Dystrophy Association  
National Alliance on Mental Illness  
National Hemophilia Foundation  
National Multiple Sclerosis Society  
National Organization for Rare Disorders  
National Patient Advocate Foundation  
Susan G. Komen  
WomenHeart: The National Coalition for Women with Heart Disease

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<sup>1</sup> American Heart Association website, “Healthcare reform principles.” Available at: [http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm\\_495416.pdf](http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_495416.pdf).

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<sup>2</sup> Avalere. *State-Run Reinsurance Programs Reduce ACA Premiums by 19.9% on Average*. March 2019. Retrieved from <https://avalere.com/press-releases/state-run-reinsurance-programs-reduce-aca-premiums-by-19-9-on-average>.



December 18, 2018

The Honorable Alex M. Azar II  
 Secretary  
 U.S. Department of Health and Human Services  
 200 Independence Avenue, SE  
 Washington, DC 20201

The Honorable Steven T. Mnuchin  
 Secretary  
 U.S. Department of the Treasury  
 1500 Pennsylvania Avenue, NW  
 Washington, D.C. 20220

**Re: State Relief and Empowerment Waivers (CMS 9936-C)**

Dear Secretary Azar and Secretary Mnuchin:

Thank you for the opportunity to submit comments on the new guidance for states applying for waivers under Section 1332 of the Affordable Care Act (ACA). The undersigned organizations urge the Department of Health and Human Services (HHS) and the Department of the Treasury (Treasury) to withdraw the guidance.

The 24 undersigned organizations represent millions of patients and consumers facing serious, acute and chronic health conditions across the country. We have a unique perspective on what individuals and families need to prevent disease, cure illness and manage chronic health conditions. Our diversity enables us to draw upon a wealth of knowledge and expertise that can be an invaluable resource in this discussion. We urge HHS and Treasury to utilize the collective insight and experience our patients and organizations offer in response to the new guidance.

In March of 2017, our organizations agreed upon three overarching principles<sup>1</sup> to guide any work to reform and improve the nation's healthcare system. These principles state that: (1) healthcare should be accessible, meaning that coverage should be easy to understand and not pose a barrier to care; (2) healthcare should be affordable, enabling patients to access the treatments they need to live healthy and productive lives; and (3) healthcare must be adequate, meaning healthcare coverage should cover treatments patients need, including all the services in the essential health benefit package.

Section 1332 waivers allow states to waive specified provisions of the ACA, provided the state's waiver plan meets four statutory guardrails: coverage must be as affordable as it would be without the waiver; coverage must be as comprehensive as it would be without the waiver; a comparable number of people must be covered under the waiver as would be without it; and the waiver must not add to the federal deficit. In 2015, HHS and Treasury issued guidance to states on how to design these waivers. The new State Relief and Empowerment Waivers guidance supersedes the 2015 guidance. Unfortunately, the new guidance neither adheres to our organizations' sound principles for reforming and improving the nation's healthcare system nor the federal law requirements it purports to interpret. As discussed in detail below, the guidance will make it easier for states to use federal taxpayer dollars to promote sub-standard plans that do not provide comprehensive and affordable coverage. This policy change tips the scales in favor of insurance products that are inadequate to meet the needs of millions of Americans with pre-existing conditions. We ask that HHS and Treasury rescind this guidance.

#### Protections for Vulnerable Populations

The 2015 guidance recognized that the ACA prohibits states from using the Section 1332 waiver program in a manner that would harm vulnerable residents, including older Americans, individuals with low incomes and those with serious health issues or who have a greater risk of developing serious health issues. Thus, while waiver applications have, until now, been evaluated based on their average impacts on all state residents, the evaluation process also has included the requirement that a waiver program ensure that the state's vulnerable residents are held harmless.

It is deeply troubling that the new guidance purports to do away with this safeguard. Notwithstanding statutory requirements, the guidance appears to condone waiver programs that make it harder for vulnerable residents to enroll in affordable, comprehensive coverage, so long as the state forecasts that more people may benefit from the program, or that the benefits for some are likely to be greater than the harm the waiver causes others.

These vulnerable populations – low-income individuals, older Americans and people with pre-existing conditions – are the patients and consumers our organizations represent, and they rely on the ACA's protections in order to access quality and affordable healthcare. These individuals often do not have other options to purchase quality and affordable healthcare coverage. Without the ACA's protections, including premium rating rules, the essential health benefits and prohibition of annual and lifetime limits on covered care, patients with pre-existing conditions would face a market that does not offer the coverage they need to manage their health, regain or maintain optimal health and productivity and

achieve better health outcomes. Additionally, absent these important protections, older Americans would face a market with unaffordable premiums and sub-standard coverage. Yet the guidance encourages states to pursue waivers likely to make these populations worse off. This is unacceptable.

#### Accessibility

The new guidance does not meet the standard of ensuring that coverage is accessible to patients and families.

The ACA is designed to encourage enrollment in minimum essential coverage (MEC)—a term created by and defined in the Act. While, for example, individual health insurance compliant with the ACA’s market reforms, as well as most job-based coverage, qualify as MEC, products such as short-term, limited-duration insurance, which is exempt from all of the ACA’s consumer protections, does not. Consistent with this statutory structure, the 2015 guidance stated that a waiver application must be rejected unless a comparable number of state residents are forecast to have MEC under the state plan as would have MEC without it.

However, the new guidance rejects this understanding, impermissibly eroding the statutory guardrails and potentially increasing the cost of coverage for people with pre-existing conditions. Relying on a broad regulatory definition of insurance promulgated pursuant to the Health Insurance Portability and Accountability Act (HIPAA) — not the ACA — the guidance purports to allow states to satisfy the coverage guardrail by counting individuals enrolled in insurance products that do not comply with the ACA’s individual and small group market consumer protections.

The Administration’s interpretation, as further elaborated in its November 29, 2018 waiver concepts discussion paper, seems to permit states to take federal dollars intended to help people enroll in comprehensive coverage and use those funds instead to spur enrollment in substandard insurance products that actively discriminate against people with preexisting conditions. This suspect interpretation could lead to states adopting policies in which fewer people are enrolled in comprehensive coverage than could be expected to have done so absent the waiver, fundamentally changing the risk pool for such coverage. This type of change could lead to a bifurcation of the market and make comprehensive coverage unaffordable for patients who need it to manage pre-existing conditions like pregnancy, cancer and heart and lung disease.

#### Affordability

The new guidance encourages states to use 1332 waivers to implement policies that would reduce enrollment in affordable coverage.

The guidance asserts that, when evaluating whether a waiver meets the affordability and comprehensiveness guardrails, it does not matter whether state residents actually enroll in affordable, comprehensive coverage. Rather, it claims a waiver may be approved based simply on “the nature of coverage that is made available” to them. This so-called “access to coverage” standard flies in the face of the federal statute. Section 1332’s affordability guardrail requires that an approved waiver be forecast to “provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable” as would be provided under the ACA in the absence of the waiver. The plain meaning of the phrase “provide coverage” — which, notably, is twice repeated in the directly adjoining statutory text that articulates the other coverage guardrails — is to permit only those waivers that will result in at least as many people actually having affordable (and comprehensive) coverage as would without the waiver.

This gross misinterpretation of the guardrails will have real consequences for patients and consumers. People with pre-existing conditions or other medical needs must be enrolled in affordable, comprehensive coverage to get the care they need without incurring massive medical debt. Moreover, this guidance threatens to undermine the risk pool for people who need more robust coverage and drive up the cost of insurance for people with pre-existing conditions. CMS should approve a waiver only if it satisfies the statutory requirement that the number of people projected to enroll in affordable, comprehensive coverage under the waiver is the same or higher than what it would be absent the waiver.

Using the misinterpretation of the coverage guardrail expressed in the latest guidance, states could use federal taxpayer dollars to steer people into sub-standard coverage. But, for patients with health conditions like lung disease, cancer, pregnancy, heart disease, rare diseases and diabetes, such coverage is likely to be inaccessible or insufficient. For people who are healthy when they enroll in coverage, the limited protections offered by such products raise the risk that they will be hit with large bills for basic preventive services or emergency care.

The new guidance appears to break with the statute in other ways that are likely to make the patients we represent worse off. Recognizing the requirement that a waiver “provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable” as the ACA, the 2015 guidance stated that waiver applications would not be approved if they reduced the number of people with coverage that provides both an actuarial value (AV) equal to or greater than 60 percent and a maximum out-of-pocket limit compliant with the ACA. These protections against excessive cost sharing are notably absent in the new guidance. Instead, the waiver concepts discussion paper invites states to apply for waivers that would increase enrollment in short-term, limited-duration plans and other coverage options that typically do not provide 60 percent AV, do not have to include an out-of-pocket maximum and can even impose annual or lifetime limits on coverage. People with serious and chronic health conditions may need expensive medical procedures, use specialty medications or require other medically necessary services that can easily lead them to hit such coverage limits. Without these protections, patients could be subject to many thousands of dollars in medical expenses that put their financial stability and medical wellbeing at risk.

The new guidance also invites states to make changes to the ACA’s subsidy structure, which provides financial assistance to individuals with incomes between 100 and 400 percent of the federal poverty level (FPL). Such changes could have major implications for the affordability of coverage for patients with pre-existing conditions and other vulnerable populations. For example, under one option suggested in the waiver concepts discussion paper, states could change the current subsidy structure to a fixed per-member-per-month contribution to a health care account based on age. This type of arrangement would provide no financial protection to patients if healthcare premiums go up (as the current subsidy structure does) and could drastically change the affordability of coverage for low-income populations. Our organizations are deeply concerned about these types of changes and the impact they will have on access to care that is required to diagnose and treat life-threatening and chronic medical conditions.

Additionally, the new guidance specifically notes that the Internal Revenue Service (IRS) could administer a waiver that provides federal tax credits to individuals with incomes below 100 percent FPL in non-expansion states, which could deter states from pursuing the ACA’s Medicaid expansion to 138 percent FPL. Medicaid expansion has been critically important for patients with serious and chronic health conditions – providing coverage that includes essential health benefits like emergency care and



hospitalizations, expands access to preventive services like cancer screenings and tobacco cessation treatment at no cost, and includes important limits on individuals' cost sharing. Furthermore, in order to meet the federal deficit neutrality guardrail, financial assistance for other residents would need to be reduced, thereby increasing premiums and out-of-pocket costs for many consumers and putting the affordability of coverage for vulnerable patients at further risk.

#### Adequacy

Finally, the new guidance allows states to make changes that will reduce enrollment in the comprehensive coverage that patients with pre-existing conditions rely upon to manage their health conditions.

First, and as discussed above, the guidance's adoption of a so-called "access to coverage" standard suggests the agencies may approve a waiver that is forecast to reduce enrollment in comprehensive (and affordable) coverage. We believe this newly created test contravenes the plain language of the statute and by its nature would make patients with pre-existing conditions worse off. This change in the standard will also allow states to ignore and fail to address the barriers that prevent many individuals from actually obtaining coverage that may be available to them, such as language barriers, health literacy issues and lack of accessible and understandable information.

The new guidance incorporates changes to states' essential health benefits (EHB) benchmark plans that the Administration finalized in the Notice of Benefit and Payment Parameters for 2019 that allow states to design EHB benchmark plans that provide less generous coverage for individuals. Additionally, the new guidance allows states to design a hypothetical benefit package specifically for the purposes of its waiver application that is not reflective of the state's actual benchmark plan, and then use this — potentially skimpier — benefit package as the baseline for determining whether waiver coverage is sufficiently comprehensive. Patients with serious and chronic diseases rely on coverage that includes robust coverage of essential health benefits to access the preventive services, prescription medications, visits with primary care and specialist providers and other treatments and services that they need to manage their conditions and stay healthy. Allowing states to manipulate the standard for assessing the Section 1332 comprehensiveness requirement in this way could directly harm patients' care.

Both the guidance and the waiver concepts discussion paper discuss options for states to customize healthcare.gov. While states could use this flexibility to improve consumers' enrollment experience, the Administration is inviting states to use this option to promote non-ACA-compliant plans, like short-term, limited-duration plans and association health plans, side-by-side with ACA-compliant plans. Such waivers would provide significant risks to consumers — increasing confusion about the coverage provided and costs associated with different plans. For example, patients diagnosed with serious medical conditions could discover the coverage they chose exposes them to uncapped financial liability or does not cover the essential health benefits that they need to manage their condition or even receive life-saving treatment.

Lastly, the waiver concepts discussion paper suggests options for states to use 1332 waivers to establish high risk pools. While our organizations support reinsurance programs that help insurers to cover enrollees with high health care costs, we are deeply concerned about the use of high risk pools for patients with expensive health conditions. High risk pools have a long history of providing inadequate coverage for the patients we represent — including pre-existing condition exclusions, waiting periods, and lifetime limits<sup>ii</sup> — and we do not want to turn the clock back to the days when patients with pre-existing conditions were locked out of comprehensive, affordable coverage on the individual market.

### Legal Issues

Our organizations believe that the interpretation of the ACA's statutory language under this guidance raises serious legal concerns. As others have noted, policy changes of this magnitude should go through a full rulemaking process.<sup>iii</sup> The guidance clearly undermines many of the statute's guardrails and other provisions that protect patients with serious and chronic conditions.

First, the guidance provides the agencies with latitude to approve a waiver that is likely to *reduce* enrollment in affordable and comprehensive coverage, as long as the proposal merely estimates that a coverage option that is affordable and comprehensive will be available. This interpretation is clearly inconsistent with the statute, which requires that a plan be forecast to "provide coverage" that is affordable and comprehensive, not simply provide the "option of" such coverage.

Second, the guidance asserts that a waiver that reduces the number of people with MEC may be approved if it offsets those coverage losses with increased enrollment in insurance products that do not satisfy the market reforms of the ACA. In particular, the guidance adopts for its test of the coverage guardrail a broad regulatory definition of insurance derived from HIPAA, not the ACA, and that includes short-term, limited-duration coverage and association health plans that are not compliant with the individual and small group market reforms of the ACA. In effect, this approach allows states to waive provisions of the ACA — including protections for people with pre-existing conditions — that are, by the terms of the statute, not waivable, putting the patients we represent at risk.

Third, the guidance redefines "comprehensive," for the purposes of satisfying the comprehensive coverage guardrail, in a way that appears to lower the bar well below what the statute permits. The new definition allows a state to create a hypothetical, unapproved EHB package, which need not reflect the state's existing benchmark plan, and use this (potentially skimpier) benefit package as the baseline for determining whether waiver coverage is sufficiently comprehensive. To the extent this approach allows states to use a benefit package that is not actually "offered through" any ACA marketplace and that cannot be certified as comprehensive by the HHS Office of the Actuary, as required by the ACA, it is inconsistent with the statute.

Finally, the ACA requires a state applying for a 1332 waiver to "enact a law . . . that provides for State actions under a waiver under [Section 1332], including the implementation of the State[']s [waiver] plan." However, under the new guidance, a state can meet this requirement if it can point to (1) a law that provides general authority to enforce the ACA; and (2) more specific executive branch action (a regulation or executive order). This interpretation is at odds with the plain language of the ACA.

### Conclusion

Our organizations represent millions of patients, individuals, caregivers and families who need access to quality and affordable healthcare coverage. Our organizations are deeply concerned that the new guidance undermines the plain language of Section 1332 of the ACA and its protections for patients with serious, acute, and chronic conditions. The new guidance does not meet our standards for affordable, accessible and adequate coverage and puts the individuals that we represent at financial and medical risk. We therefore urge HHS and Treasury to immediately withdraw the proposed guidance. Thank you for the opportunity to provide comments.

Sincerely,

Adult Congenital Heart Association  
American Cancer Society Cancer Action Network  
American Heart Association  
American Liver Foundation  
American Lung Association  
Arthritis Foundation  
Chronic Disease Coalition  
Cystic Fibrosis Foundation  
Epilepsy Foundation  
Global Healthy Living Foundation  
Hemophilia Federation of America  
Immune Deficiency Foundation  
Leukemia & Lymphoma Society  
Lutheran Services in America  
March of Dimes  
Mended Little Hearts  
Muscular Dystrophy Association  
National Alliance on Mental Illness  
National Hemophilia Foundation  
National Multiple Sclerosis Society  
National Organization for Rare Disorders  
National Patient Advocate Foundation  
Susan G. Komen  
WomenHeart: The National Coalition for Women with Heart Disease

CC: The Honorable David J. Kautter, Assistant Secretary for Tax Policy  
U.S. Department of Treasury

The Honorable Seema Verma, Administrator,  
The Centers for Medicare and Medicaid Services

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<sup>i</sup> American Heart Association website, “Healthcare reform principles.” Available at:

[http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm\\_495416.pdf](http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_495416.pdf).

<sup>ii</sup> Pollitz, Karen. High Risk pools for Uninsurable Individuals. Kaiser Family Foundation. February 22, 2017. Available at: <https://www.kff.org/health-reform/issue-brief/high-risk-pools-for-uninsurable-individuals/>.

<sup>iii</sup> Christen Linke Young, Brookings Institution, “The Trump administration side-stepped rulemaking processes on the ACA’s State Innovation Waivers—and it could make their new section 1332 guidance invalid.” Available at: <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2018/11/28/the-trump-administration-side-stepped-rulemaking-processes-on-the-acas-state-innovation-waivers-and-it-could-make-their-new-section-1332-guidance-invalid/>.