U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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Washington, DC 20548

July 6, 2016

The Honorable Orrin Hatch
Chairman
Committee on Finance
United States Senate

Patient Protection and Affordable Care Act: Information on Approval Process for State Innovation Waivers

Dear Mr. Chairman:

The Patient Protection and Affordable Care Act (PPACA) includes provisions intended to increase the number of Americans who have health coverage and outlines a shared role between states and the federal government for doing so.[1] For example, PPACA required that individuals maintain health insurance coverage and required the establishment in every state of health insurance exchanges—also known as marketplaces—through which up to 11.4 million individuals are estimated to receive coverage in 2016.[2] To allow for state innovation in providing their residents with access to health insurance while retaining the basic protections of PPACA, section 1332 of the statute permits states to seek federal approval to waive certain key requirements under the law (referred to as state innovation waivers or 1332 waivers).[3] Under 1332 waivers, for example, states may seek approval to waive the requirements that individuals maintain health insurance coverage, that exchanges perform certain functions, and that benefits of plans offered through the exchanges meet certain standards. States may also seek approval to waive PPACA requirements governing federal subsidies to assist qualifying low-income individuals in affording coverage purchased through exchanges; these subsidies are estimated to total $45 billion in 2016. However, PPACA requires that state 1332 proposals meet four approval criteria. Specifically, a state proposal must demonstrate that the waiver will result in coverage that is at least as available, comprehensive, and affordable as would have existed without the waiver, and that the waiver will not increase the federal deficit.

The Department of Health and Human Services (HHS) and the Department of Treasury (Treasury; hereafter referred to together as the Departments) are jointly responsible for

[1]Pub. L. No. 111-148, 124 Stat.119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA), Pub. L. No. 111-152, 124 Stat. 1029 (2010). For the purposes of this report, references to PPACA include the amendments made by HCERA.

[2]The Department of Health and Human Services commonly refers to the exchanges as marketplaces. Where we discuss exchanges in this report, we are referring to the individual exchanges and the small business exchanges required under PPACA. For the Department's estimate on the number of individuals expected to receive coverage through the exchanges, see Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Issue Brief: How Many Individuals Might Have Coverage at the End of 2016?* (Washington D.C.; October 2015).

[3]Pub. L. No. 111-148, § 1332, 124 Stat. 119, 203-206 (2010) (codified at 42 U.S.C. § 18052).

reviewing and approving states' 1332 waiver proposals, which they have discretion to approve provided the proposals meet the statutory approval criteria. Approved waivers can take effect for coverage beginning as early as January 2017.[4] The Departments issued final regulations in 2012 establishing the 1332 waiver application process and additional guidance in December 2015 on what states need to provide to demonstrate that a proposed waiver meets the statutory criteria and how the proposed waivers will be evaluated.[5] According to the Departments, as of May 2016, one state had an application pending.

You asked that we provide information on the status of the Departments' implementation of the review and approval process for 1332 waivers. For this report, we provide information on HHS's and Treasury's approach to:

(1) applying the statutory approval criteria, and

(2) coordinating the review and approval of 1332 waiver proposals across HHS, Treasury, and their related agencies.

To address our objectives, we reviewed federal regulations and guidance issued in 2012 and 2015 respectively. To supplement our review of the regulations and guidance, we interviewed HHS and Treasury officials about their planned approach for assessing state waiver proposals, including the rationale for requirements related to assessing compliance with the statutory criteria and procedures for coordinating reviews across the departments and their respective agencies. We also inquired about the nature and status of any state applications for 1332 waivers. We interviewed stakeholder groups—the National Governor's Association, the National Association of Medicaid Directors, and the National Academy for State Health Policy—about states' views of the Departments' review and approval policies for 1332 waivers.

We conducted this performance audit from February 2016 to July 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

HHS and Treasury have established a number of controls in the waiver review process that seek to ensure approved waivers meet the statutory criteria of preserving health coverage and controlling federal costs. For example, in applying the approval criteria included in PPACA that a state waiver provide coverage to at least a comparable number of residents and that the benefits be at least as comprehensive and affordable as in the absence of the waiver, HHS and Treasury required that the state assess the effect not only on the overall population, but also on vulnerable subgroups, such as elderly individuals. Furthermore, the Departments established a number of controls in assessing whether the proposed waiver is deficit neutral, that is, that it does not increase the federal deficit. For example, the Departments will consider not only the

[4]Exchange coverage generally begins on January 1st of each calendar year. There is an annual open enrollment period for exchange coverage, which in 2015 ran from November 1, 2015, through December 15, 2015, for coverage effective on January 1, 2016. States implementing 1332 waivers affecting coverage in 2017 may need to implement those changes prior to the annual open enrollment period.

[5]See 77 Fed. Reg. 11,700 (Feb. 27, 2012) (codified at 31 C.F.R. pt. 33 and 45 C.F.R. pt. 155); 80 Fed. Reg. 78,131 (Dec. 16, 2015).

increases to federal costs for exchange coverage but also whether the proposal will increase federal costs for other types of coverage, such as Medicaid, the joint federal-state health care financing program for low-income and medically needy individuals. As of May 2016, the Departments had not approved any waivers. Consequently, there are no waivers available to illustrate the types of approvable proposals or how the Departments applied controls.

HHS and Treasury officials stated that they have been coordinating between and within their Departments to help states as they develop the concepts for their waiver proposals prior to submitting their applications. In addition, the Departments issued joint regulations and guidance establishing the high-level roles of the Departments in the waiver review and approval process. As of May 2016, officials told us the Departments were still in the process of developing more specific procedures for coordinating. For example, HHS officials reported that the Department is developing assessment tools to be used by both Departments during review and approval. Officials also told us that the Departments are taking a flexible approach to setting procedures in recognition that they may need to evolve as the Departments gain experience with each waiver application submitted.

Background

Starting in January 2014, PPACA required that most U.S. citizens and legal residents maintain health coverage with minimum essential benefits or pay tax penalties. The law also required the establishment of exchanges in every state so that individuals and small businesses could purchase such coverage, referred to as individual exchanges and small business exchanges, respectively. States may elect to establish and operate an exchange, known as a state-based exchange (SBE), or allow HHS to do so within the state, known as a federally facilitated exchange (FFE). As of March 2016, 17 states operated SBEs and 34 states had FFEs for their individual exchanges.[6] Qualified health plans offered through the exchange are required to meet certain benefit design and other standards. For example, plans must cover hospitalization and prescription drugs. PPACA also provides federal subsidies to help qualifying individuals afford coverage in the form of premium tax credits and cost-sharing reductions. Premium tax credits may be paid to issuers of coverage in advance. The reconciliation of advanced payments of the tax credit with the amount allowed occurs when qualifying individuals file their annual income taxes with the Internal Revenue Service within Treasury.

Section 1332 of PPACA authorizes HHS and Treasury to approve state proposals to waive specified PPACA requirements related to, among other things, the maintenance of insurance coverage for individuals, exchange functions, and subsides for exchange coverage. See Table 1. Authority for approving the waivers is divided between HHS and Treasury depending on the requirements a state is seeking to waive. Specifically, section 1332 of PPACA authorizes HHS to waive specifically identified parts or sections of PPACA and authorizes Treasury to waive specifically identified sections of the Internal Revenue Code.[7]

[6]FFEs use a federal information technology (IT) platform. Certain states with SBEs also use the FFE's IT platform to perform certain exchange functions, such as determining eligibility or for enrollment. As of March 2016, 4 states with SBEs relied on the federal exchange platform for certain enrollment functions.

[7]The Secretary of HHS is authorized to waive section 1402 and Parts I and II of subtitle D of PPACA. The Secretary of Treasury is authorized to waive sections 36B, 4980H, and 5000A of the Internal Revenue Code of 1986. The Departments may not waive a requirement that does not appear in one of listed parts or sections, such as PPACA's prohibition against the use of an individual's health status to determine premium rates for insurance offered on an exchange, which appears in title I, subtitle C, part I of the Act.. See 42 U.S.C. § 18052(a)(2), (a)(6), (c)(2) and 42 U.S.C. § 300gg(a)(1).

Table 1: Types of Requirements That May Be Waived under Section 1332 of the Patient Protection and Affordable Care Act

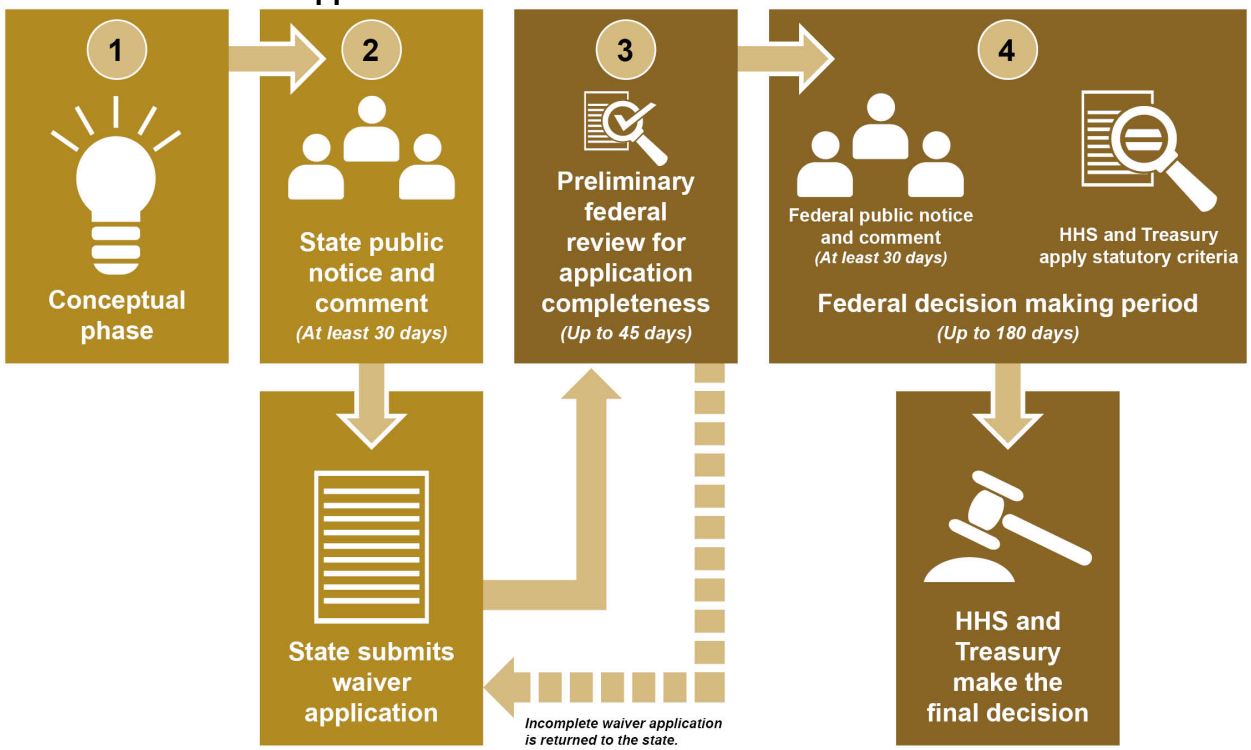
Type of Requirements	Description
Individual mandate	Requires most citizens and legal residents of the United States to maintain health insurance that qualifies as minimum essential coverage for themselves and their dependents or pay a tax penalty. Certain individuals—for example, those with qualifying religious exemptions—are exempt from the mandate and penalties.
Employer penalties	Imposes tax penalties on large employers if they fail to offer health insurance to their full-time employees or if they offer coverage that does not meet certain standards for benefits covered or affordability. Moreover, a tax penalty is imposed if at least one full-time employee obtains a premium tax credit.[a]
Exchanges	Requires that exchanges be established in every state through which individuals and small employers can purchase coverage and contains requirements for exchange functions, such as maintaining web portals for individuals and small businesses to access the exchange and call-centers to provide customer service.
Covered benefits	Requires that plans offered on the exchange cover an array of essential health benefits including emergency services, maternal and newborn care, and mental health care, among others.
Premium tax credits	Establishes premium tax credits available to eligible individuals with household incomes between 100 and 400 percent of the federal poverty level. Individuals eligible for Medicaid or other minimum essential coverage, such as qualifying employer-sponsored coverage, are not eligible for the premium tax credit.
Cost-sharing reductions	Provides for cost-sharing reductions to reduce out-of-pocket costs, such as deductibles and copayments, for eligible individuals with household incomes between 100 and 250 percent of the federal poverty level.

Source: GAO statutory analysis. I GAO-16-637R

[a]26 U.S.C. § 4980H. Federal law defines a large employer as having an average of 51 or more employees during the preceding calendar year; however, states may apply this definition based on an average of 101 or more employees. See 42 U.S.C. §§ 18024(b), 300gg-91(e).

The Departments play a shared role in helping states develop 1332 waiver proposals during the conceptual phase of the waiver process and reviewing and approving proposals. Once a state has developed a proposal, the state is required to seek public comment before submitting an application to the federal government. According to their 2012 regulations, upon submission, HHS and Treasury will perform a preliminary review to assess the completeness of the application. Upon determining that the application is complete, the Departments will seek public input during a federal public notice and comment period. HHS and Treasury will then assess the proposal against the statutory criteria during the federal decision making period. See figure 1.

Figure 1: Departments of Health and Human Services' (HHS) and Treasury's (Treasury) Section 1332 Waiver Approval Process



1. The states are encouraged to contact HHS and Treasury to discuss specific waiver proposals and to establish a reasonable timeframe for the submission of an application and the effective date of an approved proposal.
2. The state must provide a public notice and comment period that is sufficient to ensure a meaningful level of public input. The state must make an application description available to the public, as well as information about how to comment and when the state has scheduled public hearings. States must hold public hearings to provide interested parties the opportunity to learn about and comment on the application.
3. HHS and Treasury make a preliminary determination about whether the application is complete. If not complete, HHS sends the state a written notice of the elements missing from the application.
4. Upon determining that an application is complete, HHS makes the waiver application and supplemental materials available to the public, and provides information about how to submit comments. Concurrently, HHS and Treasury assess the state's waiver proposal, applying the four approval criteria. The Departments also determine the amount of federal funds that would be available to states to implement the waiver. PPACA requires that the Departments make a decision about whether to approve the state's waiver proposal within 180 days of receiving a complete application.

Source: GAO. | GAO-16-637R

The federal decision making period is the critical part of the review process in which HHS and Treasury assess whether a state's waiver proposal meets the statutory criteria. PPACA established four criteria that state proposals for 1332 waivers must meet in preserving the coverage and affordability goals of the statute.

1. **Coverage of a comparable number of people:** the state's proposal must provide coverage to at least a comparable number of the state's residents as would be receiving coverage absent the waiver.

2. **Comprehensiveness of benefits:** the scope of health benefits under the waiver must be at least as comprehensive as qualified health plans, which are required under PPACA to cover certain benefits, including hospitalization, laboratory, and mental health services.[8]
3. **Affordability:** coverage and out-of-pocket spending for state residents is at least as affordable as it would have been absent the waiver.
4. **Deficit Neutrality:** the waiver must not increase the federal deficit.

The Departments' 2012 regulations and 2015 guidance outline a state's responsibility in demonstrating that their waiver proposal meets these four criteria, including the data and analysis required.[9]

For some waiver proposals, another component of the federal decision making period is determining the amount of federal funds available to states to implement the waiver. If an approved section 1332 proposal waives premium tax credits and cost-sharing reductions, then federal funds in the amount that the federal government would have spent on cost-sharing reductions, premium tax credits, and small business tax credits for eligible individuals and small employers in the absence of the waiver may pass through to the state for purposes of implementing the waiver. These funds are referred to as federal pass-through funding.[10] HHS and Treasury are required to annually determine the aggregate amount of pass-through funding.

When a state submits a 1332 waiver application, it can submit it concurrently with proposals for other types of waivers, as required by PPACA. For example, if a state proposes changes to both its exchange coverage and its Medicaid program, it may submit a coordinated application for the 1332 and Medicaid waivers.[11] Among other types, Medicaid waivers include waivers referred to as 1115 demonstrations, which allows HHS to waive certain Medicaid requirements for purposes of allowing states to test and evaluate new approaches to delivering and financing care.

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[8]PPACA requires that qualified health plans offered on the exchange provide 10 essential health benefits, which are (1) ambulatory patient services, (2) emergency services, (3) hospitalization, (4) maternity and newborn care, (5) mental health and substance use disorder services (including behavioral health treatment), (6) prescribed drugs, (7) rehabilitative and habilitative services and devices, (8) laboratory services, (9) preventive and wellness services and chronic disease management, and (10) pediatric services, including oral and vision care. See 42 U.S.C. § 18022(b).

PPACA requires that the Office of the Actuary within the Centers for Medicare & Medicaid Services certify that proposed coverage under a 1332 waiver is at least as comprehensive as coverage offered through exchanges.

[9]77 Fed. Reg. 11,700 (Feb. 27, 2012) (codified at 31 C.F.R. pt. 33 and 45 C.F.R. pt. 155); 80 Fed. Reg. 78,131 (Dec. 16, 2015). In April 2016, HHS issued additional guidance on the use of 1332 waivers in meeting the requirements for small business exchanges.

[10]In developing an estimate of the federal pass-through funds, HHS and Treasury will take into account experience in the relevant state as well as similar states. Although the Departments will develop the estimate, states must provide analysis and supporting data, subject to the Departments' standards for state data, to inform the estimate.

[11]Medicaid is a joint federal-state health care financing program, administered largely by the states within broad federal parameters, for certain low-income and medically needy individuals. States can apply for a variety of Medicaid waivers to test new approaches to delivering and financing health care, such as waivers that allow states to cover a broader range of home and community-based services for certain populations. States must apply to HHS for approval for their Medicaid demonstrations, each requiring a separate approval process. States can also apply for other types of waivers, for example, ones that allow them to test models of care to improve the quality of care for individuals who are dually eligible for both Medicaid and Medicare, the federal health insurance program serving individuals aged 65 and older, individuals under 65 with certain disabilities, and individuals diagnosed with end-stage renal disease.

The 1332 waivers can be approved for up to five years, after which, they may be renewed subject to federal approval. States with approved waivers are required to submit regular reports, including annual reports on the waivers' ongoing compliance with the statutory criteria, and are subject to periodic evaluations by the Departments.

HHS and Treasury Established Waiver Controls That Seek to Ensure State Proposals Meet Statutory Criteria

HHS and Treasury established controls in the review and approval process for state 1332 waiver proposals. These controls seek to ensure waivers satisfy the statutory criteria related to preserving health coverage and controlling federal costs. The effectiveness of the controls as established by HHS and Treasury will depend on how they are implemented. Examples of such controls are as follows:

- **Waiver Proposals Must Consider the Impact on Vulnerable Populations:** In applying the three coverage criteria, HHS and Treasury require the state to consider impacts of its proposed waiver on both the overall state population and on different subgroups of vulnerable state residents. As part of its application, the Departments require a state to demonstrate the waiver's effect on the low-income, elderly, and the chronically ill. Consequently, even if a state can demonstrate that a waiver meets the criteria for its overall population, if the waiver reduces coverage, comprehensiveness, or affordability for any of these subgroups the waiver would fail to meet the criteria, and HHS and Treasury would not approve the waiver proposal. HHS and Treasury told us that this approach avoids the potential of their approving waivers that redistribute coverage away from these vulnerable populations, which could result from only considering the effects on the overall population.

- **Waiver Proposals Must Conform to Certain Standards in Demonstrating Deficit Neutrality:** In assessing whether a section 1332 waiver proposal does not increase the federal deficit, HHS and Treasury have instituted various controls. For example:
    - States must consider and include in their proposals how the proposed waiver will affect federal costs for other types of health coverage, such as Medicaid and the State Children's Health Insurance Program, and the effect on federal administrative costs. By including the effect of the proposed waiver on other federal costs, this control may prevent states from shifting costs to other federal health care programs.
    - HHS and Treasury will only consider the effects of changes to state policy that can be made under existing state law. HHS and Treasury will not consider effects of policy changes that are contingent on future state action such as, for example, proposed state legislation that has not yet been enacted. HHS and Treasury officials told us that this control will provide more reliable estimates of federal spending on coverage absent the waiver, an essential step in the state's analysis to demonstrate that the proposed waiver is deficit neutral.
    - HHS and Treasury will not allow states to use savings from another federal waiver, whether proposed or current, to meet the deficit neutrality criteria for a 1332 waiver. For example, if a state proposed a change to its Medicaid program under a section 1115 waiver that the state estimates will save $1 billion in federal spending, the state cannot use that $1 billion in estimated savings to meet the deficit neutrality criteria for the 1332

waiver, even if submitting a coordinated application.[12] HHS and Treasury officials told us that section 1332 waivers and Medicaid waivers are separate programs with separate approval processes and approval criteria, and, as such, these waivers will be assessed independently.

- **Waiver Proposal Methods and Data Must Conform to Certain Standards:** HHS and Treasury established standards for the data that states must provide and the analytical methods that they must use to demonstrate compliance with the statutory criteria in their waiver proposals. For example, the Departments require that states have an actuary certify the analysis demonstrating the number of individuals covered, comprehensiveness of benefits, and affordability of coverage. The Departments also require the state to use federal estimates of population growth, economic growth, and health care cost growth—state-specific data and assumptions are allowed only in cases where the state is expected to experience substantially different trends from the nation. The Departments require states to document their rationale for any deviation from federal estimates.

In addition, HHS and Treasury have identified operational considerations that will limit the types of waiver proposals the Departments will approve. Specifically, due to operational limitations related to the federal exchange IT platform and to the administrative processes of the IRS, certain types of waiver proposals will not be feasible to implement, as follows:

- Any waiver that requires changes to the federal exchange IT platform would not be feasible to implement because the platform cannot accommodate different rules for different states at this time. Changes to the calculation of premium tax credits, as well as applying state-specific enrollment periods, are examples of changes that cannot be accommodated for this reason.[13] Therefore, for states using the federal exchange platform—as of March 2016, this included 38 states using the federal platform for their individual exchanges—it is not currently feasible to approve waivers that include those changes.[14]
- A waiver that requires the IRS to administer a different set of eligibility rules—for example, for premium tax credits across states—would not be feasible to implement as the IRS is generally unable to customize eligibility requirements for different states. The Departments advised that if a state wants to modify one of the tax provisions, it should consider proposing waiving the provisions entirely and relying on a state-administered tax program to implement its modified eligibility requirements. However, the 2015 guidance also noted that waiving

[12]By excluding estimated savings from a Medicaid waiver, any control weaknesses underlying these estimated savings would not affect the deficit neutrality determination under a 1332 waiver.

In submitting a Medicaid demonstration waiver proposal under Section 1115 of the Social Security Act, states are required to estimate the effects of the waiver on federal spending. HHS has controls in place to limit federal costs under such waivers. However, our past work has found that HHS's review of states' spending estimates in their Medicaid waiver proposals lacked assurance that these waivers would not increase federal costs. See *Medicaid Demonstration Waivers: Approval Process Raises Cost Concerns and Lacks Transparency*, GAO-13-384 (Washington, D.C.: June 25, 2013), and *Medicaid Demonstrations: HHS's Approval Process for Arkansas's Medicaid Expansion Waiver Raises Cost Concerns*, GAO-14-689R (Washington, D.C.: Aug. 8, 2014).

[13]The annual open enrollment period for exchange coverage is the same for all states with an FFE or that use the FFE platform for enrollment. Individuals cannot enroll for exchange coverage at other times unless they experience a change that qualifies them for a special enrollment period.

[14]These 38 states include 34 states that have FFEs and 4 states whose SBEs rely on the federal IT platform.

provisions entirely may still create administrative costs to the IRS. Those costs would be taken into account in determining whether or not the waiver application is deficit neutral.

Stakeholder groups representing state Medicaid and exchange officials told us that, while some states continue to explore options under 1332 waivers, they believe HHS's and Treasury's application review controls and their operational considerations may considerably limit state waiver proposals. As a result, they anticipated few states would pursue 1332 waivers in 2016. For example, representatives from these stakeholders told us:

- Given that the December 2015 guidance precludes states from using savings from another federal waiver to meet the deficit neutrality criteria for a 1332 waiver, states may decide not to pursue waiver proposals that seek to combine section 1332 and Medicaid waivers to expand coverage to low-income individuals. Representatives told us that states may be concerned that such proposals may not be able to meet the deficit neutrality criteria for the 1332 waiver independently of the Medicaid waiver.
- Operational considerations, particularly the inability of the federal exchange IT platform to accommodate certain changes, may preclude a majority of states with an FFE from applying for a waiver. HHS explained that those states may develop their own systems to make changes to eligibility and enrollment; however, stakeholders questioned whether those states would have the resources to develop their own systems.[15]

The types of state waiver proposals that HHS and Treasury will approve are not yet known. As of May 2016, only one state had submitted an application, and the Departments had not completed their review of the proposal. Consequently, there are no waivers available to illustrate the types of approvable proposals or how the Departments applied their controls. The two states that HHS and Treasury characterized as being furthest along in developing proposals—Vermont, which submitted an application in April 2016, and Hawaii, which had posted its proposal for public comment—were seeking approval for relatively targeted reforms.[16] Neither state is requesting a waiver with implications for its exchange coverage for the individual market. Rather, both states seek to waive requirements for a small business exchange and, instead, propose to allow small business employers to continue to buy coverage for employees directly from insurers. Both states have cited concerns about the financial viability and operational complexities of a small business exchange, given their relatively small markets.

HHS and Treasury Are Developing Procedures to Coordinate During Review and Approval

HHS and Treasury officials told us that they have been coordinating between and within their departments to help states in the conceptual phase of the 1332 waiver proposal process. As of May 2016, HHS and Treasury told us that the Departments have had joint conceptual discussions with two states—Vermont, which submitted a proposal for a review, and Hawaii. They also told us that HHS is in regular contact with states, including those with SBEs, and has had informal discussions with states regarding section 1332 waivers. According to these officials, the Departments coordinated the conceptual discussions by assuring that relevant

[15]Federal funding that was previously available to states to establish exchanges, including developing exchange IT systems, is no longer available for new grants and any unused funds that have been awarded will expire no later than the end of 2017.

[16]HHS and Treasury officials told us Vermont initially submitted a waiver application in March, but subsequently rescinded it and resubmitted it in April.

agencies within each Department were involved in the consultation. For example, officials from the IRS told us that when Vermont was considering a potential waiver proposal, Treasury asked IRS to participate in the conceptual phase conference calls involving the state, HHS, and Treasury.

The regulations and guidance issued jointly by HHS and Treasury established high-level roles of the Departments in the review and approval process, and officials told us that the Departments will closely coordinate during reviews. Department officials told us that they also coordinated with other federal partners, for example the Department of Labor and the Office of Management and Budget, to develop these joint policies.[17] As of May 2016, HHS and Treasury officials told us that they will jointly assess all waiver applications' compliance with all approval criteria, acknowledging that a collaborative approach is necessary because of the inter-related requirements states may be seeking to waive. For example, although a proposal to waive premium tax credits falls under Treasury's purview, the proposal could nonetheless have implications for other health care programs and, therefore, Treasury would need to consult HHS on the review of the proposal. Officials also noted that the extent of the collaboration needed may vary depending on the proposal.

As of May 2016, the Departments were in the process of developing more specific procedures for coordinating review and approval of waiver proposals across Departments. According to officials, HHS was in the process of developing resources, including tools and protocols, that will be used as part of the application review process; for example, those that will be used to assess whether applications are complete. Officials told us that the Departments will share the same tools to assess state proposals. HHS plans for these tools to be reviewed by the Departments and other federal partners and to be refined as necessary. As of May 2016, the Departments did not have other examples of procedures that might be developed, and the Departments did not have target timeframes for having procedures in place. Officials told us that they are taking a flexible approach to setting procedures, recognizing that they will need to be responsive to the needs of each state, and that the protocols and procedures will evolve as HHS and Treasury gain expertise with each application.

HHS was also in the process of developing procedures to coordinate within its agencies for reviewing 1332 waivers, including with its Medicare and Medicaid divisions. HHS officials told us that HHS staff with Medicaid and Medicare expertise will be included in the assessment of whether a waiver proposal has implications for the beneficiaries or the federal costs of those programs. According to officials, as of May 2016, HHS was in the process of developing procedures to ensure those divisions are included in the review. In addition, for 1332 waiver proposals submitted in conjunction with a Medicaid waiver application, HHS officials said that they have not developed any procedures to align the timing of the reviews or coordinate communication with the state beyond those which were established in the 2012 regulations. The regulations indicate that coordinated applications should be submitted through HHS and that HHS will coordinate the 1332 review as necessary with Treasury, but do not include procedures for coordinating the 1332 review with other waiver reviews. Officials reiterated that although states can submit a coordinated application, reviews of 1332 waiver proposals will be independent of the review of other waiver proposals, as separate approval processes apply

[17]Officials reported that they have consulted with the Department of Labor (DOL) and will continue to do so about issues related to employer-based coverage. Specifically, they will coordinate with the DOL about whether waiver proposals may require waivers of or preempt provisions of the Employee Retirement Income Security Act of 1974, which is enforced by DOL.

under different waiver authorities. Stakeholder representatives told us they believe that communication within HHS will be important for efficient review of coordinated applications.

Agency Comments

We provided HHS and Treasury with a draft of this report. HHS and Treasury provided technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services and the Secretary of Treasury, appropriate congressional committees, and other interested parties. The report will also be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or iritanik@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this correspondence. Other key contributors to this correspondence included Susan Barnidge, Assistant Director; Shamonda Braithwaite, Jasleen Modi, Laurie Pachter, Vikki Porter, and Emily Wilson.

Sincerely yours,

Katherine M. Iritani
Director, Health Care

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