



## Quick Review

# Section 1115 Waiver Requests: Transparency and Opportunity for Public Comment

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Section 1115 of the Social Security Act authorizes the Secretary of the Department of Health and Human Services (HHS) to waive some requirements of the Medicaid Act to allow states to test novel approaches to improving medical assistance for low-income people through an experimental, pilot, or demonstration project.<sup>1</sup> The statute and implementing regulations contain detailed requirements regarding transparency and public participation during the development, approval, and monitoring of a demonstration.<sup>2</sup> For more detailed information on this topic, see NHeLP's [Section 1115 Waiver Requests: Transparency and Opportunity for Public Comment](#).

### Application and Approval Process

#### *State Notice/Comment & Public Hearing Period*

Before submitting an application to CMS for an initial demonstration or extension of an existing demonstration, states must provide a 30-day public notice and comment period.<sup>3</sup> The public notice must contain a “comprehensive description of the application” that is detailed enough to “ensure meaningful input from the public.” The notice must also include, among other things: where to access copies of the application; how and when to submit written comments; and when and where the state will hold public

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<sup>1</sup> 42 U.S.C. § 1315(a). For more information, see NHeLP's Waivers of Medicaid Requirements – A Quick Review, <http://www.healthlaw.org/publications/browse-all-publications/waivers-medicaid-requirements-review>.

<sup>2</sup> See 42 U.S.C. § 1315(d); 42 C.F.R. Pt. 431.

<sup>3</sup> 42 C.F.R. § 431.408(a).

hearings on the application.<sup>4</sup> The state must post the notice on its website and distribute it through other means, as outlined in the regulations.<sup>5</sup>

States must hold two public hearings on the application, on separate days and at separate locations, at least 20 days before submitting the application to CMS.<sup>6</sup>

### *Application Submission*

To be considered complete, an application must include documentation of the state's compliance with the public notice and comment requirements, as well as other information about the demonstration, as specified in the regulations.<sup>7</sup> CMS may request, or the state may propose, modifications to an application. If the modifications result in substantial changes, CMS may, at its discretion, direct an additional 30-day public comment period.<sup>8</sup>

States must submit a request to extend an existing state-wide comprehensive demonstration within certain timeframes as follows: (1) for an initial extension, one year before the demonstration would otherwise expire; (2) for a subsequent extension, 120 days before the initial extension would otherwise expire (unless the waiver approval indicated a different timeframe).<sup>9</sup> If an extension application would make substantial changes to the existing demonstration, CMS may, at its discretion, treat the request as an initial application for a new demonstration.<sup>10</sup>

### *Federal Notice/Comment Period and CMS Review*

After receiving an application, CMS has 15 days to tell the state either: (1) the application is incomplete and what is needed to complete it; or (2) the application is complete and that the 30-day federal public notice and comment period has started.<sup>11</sup> The initiation of the 30-day comment period does not preclude CMS from determining that, based on further review, additional information is required from the state.<sup>12</sup>

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<sup>4</sup> *Id.* § 431.408(a)(1).

<sup>5</sup> *Id.* § 431.408(a)(2).

<sup>6</sup> *Id.* § 431.408(a)(3).

<sup>7</sup> *See* 42 C.F.R. §§ 431.412(a)(1) (initial demonstration application); 431.412(c)(2) (extension application).

<sup>8</sup> 42 C.F.R. § 431.412(a)(2) (initial demonstration application); § 431.412(c)(3) (extension application).

<sup>9</sup> 42 U.S.C. § 1315(e)(2), (f)(1); 42 C.F.R. § 431.412(c).

<sup>10</sup> *Id.* § 431.412(c)(1).

<sup>11</sup> *Id.* §§ 431.416(a), 431.412(b)(1)-(2).

<sup>12</sup> *Id.* § 431.412(b)(1)(i).

CMS must publish certain information on its website, including: the written notice starting the public comment period; the application (including supporting documents and concept papers submitted as part of the application); the proposed effective date of the demonstration; how and when the public may comment; all written comments submitted; and at regular intervals, relevant information, such as status updates.<sup>13</sup> CMS must also maintain and post on its website an administrative record.<sup>14</sup>

In general, CMS may not make a final decision on any application until at least 45 days after sending the written notice starting the public comment period.<sup>15</sup> However, CMS may grant a temporary extension for the period during which an extension application is under review, without regard to when the state submitted the application.<sup>16</sup>

CMS may waive any part of the state or federal notice and comment process to expedite a decision on a demonstration application designed to address unforeseen circumstances resulting from a natural disaster, public health emergency, or other sudden emergency that directly threatens human lives.<sup>17</sup>

Under the statute, CMS must complete its review of an extension application within a certain timeframe, which differs depending on whether the state is seeking an initial extension of a state-wide comprehensive demonstration or a subsequent extension.<sup>18</sup>

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<sup>13</sup> *Id.* §§ 431.416(b)-(d), 431.412(b)(3).

<sup>14</sup> *Id.* § 431.416(f).

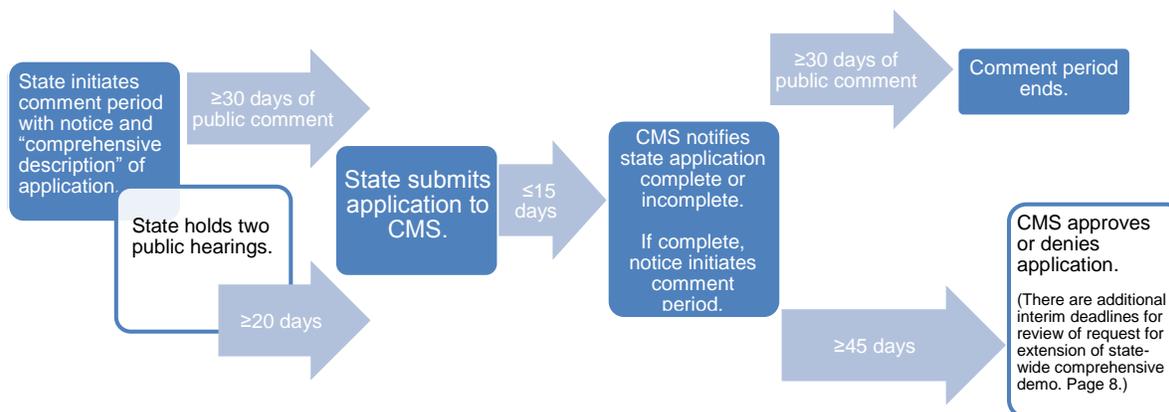
<sup>15</sup> *Id.* § 431.416(e).

<sup>16</sup> *Id.* § 431.412(c)(4).

<sup>17</sup> *Id.* § 431.416(g).

<sup>18</sup> *See* 42 U.S.C. §§ 1315(e)(3), (f)(2)-(5).

## Summary of Process & Timeframes



## Monitoring and Enforcement of Approved Demonstrations

Unless CMS expressly grants a waiver of a provision in § 1396a when approving a demonstration application, the state must continue to comply with the provision.<sup>19</sup> In addition, states must comply with the special terms and conditions of the demonstration.<sup>20</sup> The regulations establish reporting and monitoring procedures designed to ensure that CMS has adequate information concerning both a state's compliance with these requirements and the effectiveness of the demonstration.

### *Post-Award Public Forums & Annual Reports*

The state must perform periodic reviews of the demonstration. Within six months after implementation begins, and on an annual basis thereafter, the state must hold a public forum to solicit comments on the demonstration's progress.<sup>21</sup> In addition, if CMS receives a complaint that a state is failing to comply with special terms and conditions, it will review the complaint and share it with the state.<sup>22</sup>

<sup>19</sup> 42 C.F.R. § 431.420(a)(1).

<sup>20</sup> *Id.* § 431.420(a)(2).

<sup>21</sup> *Id.* § 431.420(c)(1).

<sup>22</sup> *Id.* § 431.420(b)(2)-(3).

The state must submit to CMS and post on its website an annual report containing specific information about the demonstration's progress, including all public comments received during the post-award public forum.<sup>23</sup>

### *Evaluations*

Given that CMS grants § 1115 waivers to enable states to pilot or experiment with new approaches, states must evaluate the results of an approved demonstration and make the evaluation available to the public.<sup>24</sup> CMS must also post evaluation materials to its website within 30 days of receiving them from the state.<sup>25</sup> Prior to conducting an evaluation, states must submit an evaluation design plan to CMS and post the plan to its website within 30 days of CMS approval.<sup>26</sup>

### *Enforcement*

The Secretary may suspend or terminate all or part of a demonstration if the state has “materially failed to comply” with the special terms and conditions. The Secretary may also withdraw approval after finding that a project is not in fact likely to achieve the purposes of the Medicaid Act.<sup>27</sup>

### **Conclusion**

The importance of the transparency and public accountability requirements has never been greater, as the Secretary of HHS recently expressed a willingness to approve demonstrations that include work requirements, eliminate presumptive eligibility, and impose greater premiums and cost-sharing than the Medicaid Act allows.<sup>28</sup> For an in-depth issue brief on this subject, see NHeLP's [Section 1115 Waiver Requests: Transparency and Opportunity for Public Comment](#).

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<sup>23</sup> *Id.* § 431.428(a)-(b).

<sup>24</sup> *See id.* § 431.424.

<sup>25</sup> *Id.* § 431.424(g).

<sup>26</sup> *Id.* § 431.424(c), (e). The deadline for this submission should be included in the special terms and conditions.

<sup>27</sup> *Id.* § 431.420(d)(1)-(2). The terms and conditions must detail a state's notice and appeal rights in the event of termination, suspension, or withdrawal of waivers or expenditure authorities. *Id.* § 431.420(d)(3).

<sup>28</sup> *See* Letter from Thomas E. Price, Secretary, Dep't of Health & Human Servs. & Seema Verma, Admin., Dep't of Health & Human Servs., Ctrs. For Medicare & Medicaid Servs., to Governors (Mar. 15, 2017).