DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

June 07, 2022

Lisa Olson
Medicaid Director
State of Wisconsin, Department of Health Services
1 West Wilson Street
Room 350; P.O. Box 309
Madison, WI 53701-0309

Dear Ms. Olson:

On March 13, 2020, the President of the United States issued a proclamation that the COVID-19 outbreak in the United States constitutes a national emergency by the authorities vested in him by the Constitution and the laws of the United States, including sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.), and consistent with section 1135 of the Social Security Act (Act) as amended (42 U.S.C. 1320b-5). On March 13, 2020, pursuant to section 1135(b) of the Act, the Secretary of Health and Human Services invoked his authority to waive or modify certain requirements of titles XVIII, XIX, and XXI of the Act as a result of the consequences of the COVID-19 pandemic, to the extent necessary, as determined by the Centers for Medicare & Medicaid Services (CMS), to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the respective programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of such requirements as a result of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse. This authority took effect as of 6:00 PM Eastern Standard Time on March 15, 2020, with a retroactive effective date of March 1, 2020. We note that the emergency period will terminate, upon termination of the public health emergency (PHE), including any extensions.

For the reasons discussed below, CMS is approving an amendment to the Special Terms and Conditions (STCs) for Wisconsin's section 1115(a) demonstration entitled, "Wisconsin SeniorCare" (Project Number 11-W-00149/5). The amendment provides expenditure authority, to the extent necessary, for state payments to providers for the administration of a COVID-19 vaccine for the limited-benefit population enrolled in the Wisconsin SeniorCare section 1115 demonstration. To the extent necessary, this expenditure authority also applies, notwithstanding section 1903(b)(1) of the Act and implementing regulations at 42 CFR 431.625(d)(3), to state payments to providers for COVID-19 vaccinations that could have been paid for under Medicare Part B, but were not, because the beneficiary was eligible for enrollment in Medicare Part B but was not enrolled in Medicare Part B. The expenditure authority will be in effect from December 14, 2020 through and including June 5, 2022. Beginning June 6, 2022, through a separate CMS

section 1115 demonstration amendment approval, Wisconsin has authority to provide coverage for Advisory Committee on Immunization Practices (ACIP)-recommended vaccinations for persons aged 65 and over, including COVID-19 vaccinations, to the extent necessary, for all persons enrolled in the demonstration.

The population eligible for the SeniorCare demonstration consists of Wisconsin residents, age 65 and older, with income at or below 200 percent of the Federal Poverty Level (FPL). To be eligible to enroll in SeniorCare, otherwise eligible individuals must not be eligible under the Medicaid state plan, with a few limited exceptions for certain limited-benefit Medicaid state plan eligibility groups. First, otherwise eligible individuals may enroll in SeniorCare even if they are also eligible for enrollment in one of the limited-benefit Medicaid state plan eligibility groups that receives medical assistance only for payment of Medicare premiums and/or cost-sharing (in other words, are eligible for enrollment in a Medicare Savings Program as Qualified Medicare Beneficiaries, Specified Low-Income Medicare Beneficiaries, Qualifying Individuals, or Qualified Disabled Working Individuals). Thus, some persons who are eligible for coverage under the Wisconsin SeniorCare demonstration are also eligible for enrollment in coverage consisting only of payment of Medicare premiums under the limited-benefit Medicaid state plan groups described in sections 1902(a)(10)(E) and 1933 of the Act. Second, otherwise eligible individuals may enroll in SeniorCare even if they are also eligible for enrollment in the limited-benefit state plan eligibility group that receives medical assistance only for tuberculosis-related benefits, as described in sections 1902(a)(10)(A)(ii)(XII) and 1902(z)(1) of the Act. Third, otherwise eligible individuals may enroll in SeniorCare even if they are also eligible for enrollment in the limited-benefit state plan eligibility group that receives medical assistance only for family planning benefits, as described in sections 1902(a)(10)(A)(ii)(XXI) and 1902(ii) of the Act. Individuals with commercial health insurance may also enroll in the SeniorCare demonstration if all other eligibility criteria are met.

Starting March 11, 2021, section 1905(a)(4)(E) of the Act (as added by section 9811 of the American Rescue Plan Act of 2021 (ARP)), and corresponding amendments to sections 1902(a)(10), 1916, 1916A, and 1937 of the Act, require states to cover COVID-19 vaccines and their administration, without cost-sharing, for nearly all Medicaid beneficiaries, including most groups receiving limited-benefit packages under the state plan or a section 1115 demonstration. This coverage is required beginning March 11, 2021, and (generally) ending on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act. The ARP amendments require states to cover COVID-19 vaccines and their administration under the Medicaid state plan for members of the eligibility groups who otherwise receive medical assistance under the state plan only for tuberculosis-related or family-planning benefits; therefore, some persons enrolled in the SeniorCare demonstration began receiving COVID-19 vaccination coverage under the state plan on March 11, 2021. However, the ARP amendments do not permit or require states to provide this COVID-19 vaccination coverage to persons who are eligible for medical assistance consisting only of payment of Medicare premiums pursuant to sections 1902(a)(10)(E) or 1933 of the Act.

This demonstration amendment provides expenditure authority, to the extent necessary, for COVID-19 vaccine administration coverage for the entire limited-benefit population enrolled in

the Wisconsin SeniorCare demonstration. CMS is approving this expenditure authority for the period from December 14, 2020, through and including the June 5, 2022. This approval period begins on the date that distribution of COVID-19 vaccines began in the United States and extends through and including the day before coverage for ACIP-recommended vaccinations for persons age 65 and over (including COVID-19 vaccinations) was added to the demonstration coverage for all SeniorCare demonstration enrollees (to the extent necessary). The amendment will thus ensure coverage of COVID-19 vaccinations for Wisconsin SeniorCare enrollees who lacked coverage for these vaccinations under the Medicaid state plan during part or all of this period, and who lacked other coverage for COVID-19 vaccinations that pays primary to Medicaid during part or all of this period. For persons enrolled in the demonstration who began receiving coverage for COVID-19 vaccinations under the Medicaid state plan on March 11, 2021, no coverage for COVID-19 vaccinations would be necessary or provided under this demonstration amendment beginning on that date. And, as discussed above, to the extent necessary, this expenditure authority will also apply, notwithstanding section 1903(b)(1) of the Act and implementing regulations at 42 CFR 431.625(d)(3), to state payments to providers for COVID-19 vaccine administration provided to persons who are eligible for but not enrolled in Medicare Part B. There will be no cost-sharing for the COVID-19 vaccination coverage under this amendment.

Currently, and during the effective period of this amendment, COVID-19 vaccines are federally purchased; therefore, the only expenditure authority necessary for this amendment is for payments for the administration of a COVID-19 vaccine.

This amendment will ensure COVID-19 vaccination coverage is available for the very limited number of beneficiaries who were enrolled in the demonstration, but not enrolled in other coverage that pays primary to Medicaid and that would cover the administration of COVID-19 vaccines, and who do not have coverage for COVID-19 vaccinations under the state plan. Because the expenditure authority applies notwithstanding section 1903(b)(1) of the Act and implementing regulations at 42 CFR 431.625(d)(3), it also includes coverage for COVID-19 vaccinations provided to persons who are eligible for but not enrolled in Medicare Part B. STC 40 of the Wisconsin SeniorCare demonstration, regarding payer of last resort, will apply to the coverage under this amendment. Consistent with federal law and with STC 40, the state will ensure that Medicaid is not covering a COVID-19 vaccination for a person in the demonstration if that vaccination was covered under other coverage that pays primary to Medicaid.

CMS has determined that the state's application is complete, consistent with the exemptions and flexibilities outlined in 42 CFR 431.416(e)(2) and 431.416(g).[1] CMS expects that states will offer, in good faith and in a prudent manner, a post-award public notice process, including tribal consultation as applicable, to the extent circumstances permit.

[1] Pursuant to 42 CFR 431.416(g), CMS has determined that the existence of unforeseen circumstances resulting from the COVID-19 PHE warrants an exception to the normal state and federal public notice procedures to expedite a decision on a proposed COVID-19 section 1115 demonstration or amendment. States applying for a COVID-19 section 1115 demonstration or amendment are not required to conduct a public notice and input process prior to submission of the application to CMS. CMS is also exercising its discretionary authority to expedite its normal review and approval processes to render timely decisions on state applications for COVID-19 section 1115 demonstrations or amendments. CMS will post all section 1115 demonstrations or amendments approved under the COVID-19 demonstration opportunity on the Medicaid.gov website.

CMS has determined that this Wisconsin COVID-19 Vaccine Administration PHE amendment to its section 1115 demonstration titled, "Wisconsin SeniorCare" is necessary to assist the state in delivering the most effective care to its beneficiaries in light of the COVID-19 PHE. The demonstration is likely to assist in promoting the objectives of the Medicaid statute because it is expected to help the state furnish medical assistance in a manner intended to protect, to the greatest extent possible, the health, safety, and welfare of individuals and providers who may be affected by COVID-19. Ensuring that there is broad coverage for COVID-19 vaccinations, including in circumstances where section 1903(b)(1) would ordinarily preclude Medicaid coverage for such vaccinations, will help further that goal.

In addition, in light of the unprecedented emergency circumstances associated with the COVID-19 pandemic and consistent with the President's declaration detailed above – and because of the time-limited nature of this demonstration amendment – CMS did not require the state to submit budget neutrality calculations for this Wisconsin COVID-19 Vaccine Administration PHE amendment. In general, CMS has determined that the costs to the federal government are likely to have been otherwise incurred and allowable. Wisconsin will still be required to monitor and evaluate the expenditure authority that CMS approved, including tracking demonstration expenditures and assessing how such outlays would facilitate the state's response to the COVID-19 PHE. Due to the highly limited scope of the changes under the amendment, CMS is incorporating this amendment as Attachment D to the STCs for the Wisconsin SeniorCare section 1115 demonstration.

Monitoring and Evaluation Requirements

Given the unique circumstances and time-limited nature of this demonstration amendment, and the fact that the entire approval period for this amendment is retroactive, CMS expects Wisconsin to undertake data collection and analyses that are meaningful but not unduly burdensome for the state, while also being consistent with the applicable provisions of 42 CFR 431.424 and 431.428. It is still important to gather evidence regarding the operation and effectiveness of this amendment, but, recognizing the challenges associated with the COVID-19 PHE and the retroactive approval period for this demonstration amendment, CMS has simplified the monitoring and evaluation requirements for this amendment. The state's streamlined monitoring and evaluation activities for this demonstration amendment, including an outline of an Evaluation Design, will be encapsulated in a Final Report, the draft of which will be due to CMS no later than eighteen months after the state's receipt of the approval of the amendment. The monitoring and evaluation requirements are reflected in Attachment D.

The Final Report should include a background description of the scope and objectives of the amendment and outline the evaluation questions, suggested ideas for which are provided in Attachment D. The Final Report should also narrate how the state would leverage the simplified expectations for data collection and analyses for this amendment, in alignment with information outlined in Attachment D, to support contextualizing and addressing the evaluation questions. Briefly, the Final Report should provide a discussion of the findings that will support understanding the successes, challenges, and lessons learned in implementing the amendment, to help inform best practices for similar situations in the future. Additionally, the state should provide summary data on demonstration expenditures under this amendment, and describe briefly how these outlays were effective at achieving the objectives of the

demonstration amendment. Finally, the Final Report should outline any challenges and limitations encountered in the planning and conduct of the monitoring and evaluation activities. Per requirements described in Attachment D, the state will post the CMS-approved Final Report to the state's Medicaid agency website within 30 days of CMS approval.

Approval of this demonstration amendment is subject to the limitations specified in this letter. The state may deviate from its Medicaid state plan requirements only to the extent that the requirements have been specifically identified as not applicable for the demonstration as specified in the list of approved authorities. This approval is conditioned upon continued compliance with the previously approved STCs which set forth in detail the nature, character, and extent of anticipated federal involvement in the project.

The award is subject to CMS receiving written acceptance of this award within 15 days of the date of this approval letter. Your project officer is Ms. Tonya Moore. Ms. Moore is available to answer any questions concerning implementation of the state's section 1115 demonstration and her contact information is as follows:

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Center for Medicaid and CHIP Services
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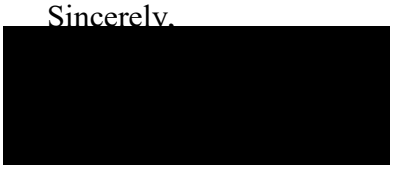
Baltimore, Maryland 21244-1850
Email: Tonya.Moore@cms.hhs.gov

We appreciate your state's commitment to addressing the significant challenges posed by the COVID-19 pandemic, and we look forward to our continued partnership on the Wisconsin SeniorCare section 1115 demonstration amendment. If you have any questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,



Deputy Administrator and Director
Center for Medicaid and CHIP Services

Enclosure

cc: Mai Le-Yuen, State Monitoring Lead, Medicaid and CHIP Operations Group

Attachment D
Time-limited Expenditure Authority and Associated Requirements for the COVID-19 Public Health Emergency (PHE) Demonstration Amendment

Expenditure Authority

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act, shall, for the period from December 14, 2020 through and including June 5, 2022, be regarded as expenditures under the State's title XIX plan.

> **COVID-19 Vaccine Administration Payments.** Expenditure authority, to the extent necessary, for state payments to providers for the administration of a COVID-19 vaccine for Wisconsin SeniorCare enrollees, from December 14, 2020 through and including June 5, 2022. To the extent necessary, this expenditure authority also applies, notwithstanding section 1903(b)(1) of the Act and implementing regulations at 42 CFR 431.625(d)(3), to state payments to providers for COVID-19 vaccinations that could have been paid for under Medicare Part B, but were not, because the beneficiary was eligible for enrollment in Medicare Part B but was not enrolled in Medicare Part B.

Monitoring and Evaluation Requirements

Evaluation Design and Final Report. Given the unique circumstances and the time-limited nature of this demonstration amendment, and the fact that the entire approval period for this amendment is retroactive, CMS has streamlined the monitoring and evaluation requirements for this amendment. While it is important to gather evidence regarding the operation and effectiveness of this amendment, CMS understands the unusual situation of the COVID-19 PHE and the challenges it presents to data collection and analyses required to comply with the systemic monitoring and robust evaluation requirements for more traditional section 1115 demonstrations. Therefore, the requirements for data collection and analyses for this amendment are structured to be meaningful and productive, and importantly, consistent with the applicable provisions of 42 CFR §§ 431.424 and 431.428, but not unduly burdensome for the state in light of the retroactive approval period for this amendment.

Specifically, the state will be required to develop a Final Report, which will consolidate the amendment's monitoring and evaluation requirements. To address the requirements in 42 CFR § 431.424(c), the Final Report will include a section clearly outlining the state's underlying Evaluation Design for the evaluation of the expenditure authority approved in this amendment. The draft Final Report will be due to CMS no later than eighteen months after the state's receipt of the approval of the amendment. CMS's section 1115 demonstration evaluation guidance "Preparing the Evaluation Report"[2] provides pertinent instructions that would be helpful in preparing the consolidated Final Report. The state should customize the content of the Final Report to align with the specific scope of the demonstration amendment.

[2] Available at https://www.medicaid.gov/medicaid/downloads/preparing-the-evaluation-report.pdf.

The state should include in the Final Report a background description of the scope and objectives of the demonstration amendment's expenditure authority. The Final Report should be structured such that the section describing the Evaluation Design of this amendment outlines the evaluation questions the state will examine as part of its evaluation, a description of the data sources the state will leverage to both contextualize and respond to these questions, and the methodologies and approaches used in the evaluation.

For this demonstration amendment, the state will test whether and how the approved expenditure authority facilitated the state's response to the COVID-19 PHE, and helped promote the objectives of Medicaid. To that end, the evaluation for this amendment will address thoughtful evaluation questions that support understanding the successes and challenges in implementing the expenditure authority. The state may use evaluation questions that will provide insight into: the populations affected by the expenditure authority under this amendment; specific policies and procedures that reduced barriers to care (e.g., the steps taken to ensure access to COVID-19 vaccines); challenges associated with implementing the amendment and engaging with beneficiaries, as well as how the state overcame these challenges, as applicable; and principal lessons learned for any future PHEs. Additionally, the state should track demonstration expenditures under this amendment, including – as appropriate – administrative and program costs and health services expenditures under the amendment, and assess how these outlays were effective at achieving the objectives of the demonstration amendment. The Final Report should also outline any challenges and limitations encountered in the planning and conduct of the monitoring and evaluation activities.

To address the evaluation questions as well as for providing contextual information to better understand the extent of the challenges presented by the COVID-19 PHE, and any unresolved or ongoing challenges the state continues to face, the state should identify and use suitable qualitative and quantitative data. The state may also use publicly available benchmark data from other federal agencies, such as the Centers for Disease Control and Prevention (CDC), on rates of COVID-19 cases and associated vaccinations, hospitalizations and deaths.[3] Overall, the Final Report should provide an understanding of the successes, challenges, and lessons learned in implementing the demonstration amendment.

In accordance with the Wisconsin SeniorCare section 1115 demonstration's STC #58 on *Public Access* pertaining to demonstration deliverables, the state is required to post the CMS-approved Final Report for this amendment to its Medicaid agency website within 30 days of CMS approval. In addition, per 42 CFR § 431.420(f), the state must comply with any requests for data from CMS and/or its federal evaluation contractors.

[3] For example, see https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html, https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm, and https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.