Application to Use Burden/Hours from Generic PRA Clearance:
Medicaid and CHIP State Plan, Waiver, and Program Submissions
(CMS-10398, OMB 0938-1148)

Generic Information Collection # 68
Section 1006(b) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) - Medicaid Assisted Treatment (MAT)

Date: October 23, 2020

Center for Medicaid and CHIP Services (CMCS)
Centers for Medicare & Medicaid Services (CMS)

A. Background

The Centers for Medicare & Medicaid Services (CMS) work in partnership with states to implement Medicaid and the Children's Health Insurance Program (CHIP). Together these programs provide health coverage to millions of Americans. Medicaid and CHIP are based in Federal statute, associated regulations and policy guidance, and the approved state plan documents that serve as a contract between CMS and states about how Medicaid and CHIP will be operated in that state. CMS works collaboratively with states in the ongoing management of programs and policies, and CMS continues to develop implementing guidance and templates for states to use to elect new options available as a result of the Affordable Care Act, or to comply with new statutory provisions such as those in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act). CMS also continues to work with states through other methods to further the goals of health reform, including program waivers and demonstrations, and other technical assistance initiatives.

B. Description of Information Collection

Section 1006(b) of the SUPPORT Act requires coverage of MAT as a new mandatory Medicaid state plan benefit for the period beginning October 1, 2020, and ending September 30, 2025. Section 1006(b) adds section 1905(ee)(1) to the Social Security Act (Act) to define MAT as:

> . . . all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders; and… includes, with respect to the provision of such drugs and biological products, counseling services and behavioral therapy.

The Food and Drug Administration (FDA) has approved the following drugs used for MAT to treat opioid use disorder (OUD): methadone, buprenorphine, and naltrexone. Only those formulations of these drugs that are approved by the FDA for MAT to treat OUD are required to be covered under the new mandatory Medicaid benefit. CMS interprets section 1905(ee)(1) of the Act to require that states include as part of the new mandatory benefit all forms of drugs and biologicals that the FDA has approved or licensed for MAT to treat OUD. There are currently no FDA-licensed biological products to treat OUD. In addition to the medications, MAT includes counseling and behavioral therapies such as individual and group therapy, peer support services, and crisis intervention services.

Section 1006(b) also allows states to assert two exceptions to timely compliance with the requirements of this provision:

First, states can seek an extension to timely compliance based on the need for state legislation to authorize a state plan amendment when that legislation cannot be secured by October 1, 2020, and the only reason the state cannot come into compliance by October 1, 2020, is due to lack of state legislation that is needed to meet the requirement.

Second, states can seek an exception if they can satisfactorily certify prior to October 1, 2020, that implementing such coverage statewide would not be feasible due to a shortage of qualified providers willing to contract with the state or the state's Managed Care Organizations (MCOs).

The state submission consists of SPA templates for item 1905(a)(29). The SPA Coverage templates for Limitations (Supplement to Attachment 3.1-A and Supplement to Attachment 3.1-B) request the following information:

1. A general assurance that the state covers MAT under the Medicaid state plan for all Medicaid beneficiaries who meet the medical necessity criteria for receipt of the service for the period beginning October 1, 2020, and ending September 30, 2025.
2. Additional assurances that a) the state covers Naltrexone, Buprenorphine, and Methadone and all of the forms of these drugs for MAT that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); and b) Methadone for MAT is provided by Opioid Treatment Programs that meet the requirements in 42 CFR part 8.
3. The service package that includes a) each service and components of each service (if applicable), along with a description of each service and component service; b) each practitioner and provider entity that furnishes each service and component service; and c) a brief summary of the qualifications for each practitioner or provider entity that the state requires including any licensure, certification, registration, education, experience, training and supervisory arrangements that the state requires.
4. The state's drug utilization controls, if applicable.
5. The state's limitations on amount, duration, and scope of MAT drugs, biologicals, and counseling and behavioral therapies related to MAT, if applicable.

Since section 1006(b) of the SUPPORT Act makes MAT a mandatory state plan benefit under section 1905(a) of the Act for the period beginning October 1, 2020 and ending September 30, 2025, states will react favorably to the availability of the templates that outline what states need to provide in their SPA submissions. The templates should facilitate prompt review and approval of states' SPAs.

C. Deviations from Generic Request

No deviations are requested.

D. Burden Hour Deduction

The total approved burden ceiling of the generic ICR is 154,104 hours, and CMS previously requested to use 82,233 hours, leaving our burden ceiling at 71,871 hours.

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the

mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialist	13-1000	36.31	36.31	72.62

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Collection of Information Requirements and Associated Burden Estimates

There is a potential universe of 56 respondents (states, D.C., and territories).

While states/territories/D.C. (hereinafter, "states") are not required to submit both templates, they are required to submit the categorically needy population template (Supplement to Attachment 3.1-A) to cover services for the mandatory categorically needy Medicaid population. States have the discretion to cover the optional medically needy population by submitting Supplement to Attachment 3.1-B. We anticipate that most if not all states will submit the categorically needy population template (Supplement to Attachment 3.1-A). CMS expects that it will take approximately 80 hours at $72.62/hr for a business operations specialist to complete and submit Supplement to Attachment 3.1-A to CMS.

For the medically needy population (Supplement to Attachment 3.1-B) we anticipate minimal state burden since states can copy and paste their responses from their Supplement to Attachment 3.1-A submission into their Attachment 3.1-B submission. In that regard we estimate it would take 30 minutes (0.5 hr) at $72.62/hr for a business operations specialist to copy/paste, review, and submit Supplement to Attachment 3.1-B to CMS.

While we estimate 56 respondents for Supplement to Attachment 3.1-A, we have no means of reliably estimating the number of respondents that will be submitting Supplement to Attachment 3.1-B. To help ensure that we are in compliance with the PRA, we are proposing a burden of 10 respondents which we believe reasonably overestimates the actual figure.

Burden Summary

The total burden for this effort follows:

Template	Respondents	Total Responses	Time per Response (hours)	Total Time (hours)	Labor Cost ($/hr)	Total Labor Cost ($)
Attachment 3.1-A (Categorically Needy Population)	56	56	80	4,480	72.62	325,338
Attachment 3.1-B (Medically Needy Population)	56	10	0.5	5	72.62	363
TOTAL	56	66	Varies	4,485	72.62	325,701

Collection of Information Instruments and Associated Instruction/Guidance Documents[1]

- SPA Coverage Template for Limitations (Supplement to Attachment 3.1-A)

  Identifies the medical and remedial services provided to the categorically needy.

- SPA Coverage Template for Limitations (Supplement to Attachment 3.1-B)

  Identifies the medical and remedial services provided to the medically needy.

E. Timeline

CMS is requesting expedited approval to make the SPA templates available to states as early as possible so that states can begin the process of preparing their submission which entails supplying requested data and/or data sources as outlined in the instructions. The SPA templates must be approved by CMS before expenditures can be claimed at the regular FMAP rates beginning October 1, 2020, for the mandatory state plan benefit of MAT.

[1] Both templates supplement our state plan collection of information request (Attachment 3.1 A) that is currently approved by OMB under control number 0938-0193 (CMS-179). In this October 2020 iteration, we are submitting both templates under this generic collection of information request (CMS-10398, OMB 0938-1148) since: (1) the templates fit under the parameters of the generic umbrella, (2) the templates are not controversial, (3) we do not anticipate negative public comment, and (4) when ready, both supplements will be removed from this 0938-1148 control number and added to the 0938-0193 control number via the standard PRA process. The purpose is to address the need for expedited approval of the supplemental data fields for the new mandatory Medicaid state plan benefit for MAT. Because of the timeframe and nature of the opioid crisis, we believe it is outside of the public's interest to follow the standard PRA process for this initial approval.