

Supporting Statement – Part A
Medical Necessity and Contract Amendments Under Mental Health Parity
CMS-10556 (OMB 0938-1280)

Background

This collection of information request is associated with our March 30, 2016 (81 FR 18390) final rule “Medicaid and Children’s Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children’s Health Insurance Program (CHIP), and Alternative Benefit Plans” (CMS–2333–F; RIN 0938–AS24)). The final rule amended the Medicaid and CHIP regulations to implement the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) that generally prevents group health plans and health insurance issuers that provide mental health or substance use disorder (MH/SUD) benefits from imposing less favorable benefit limitations on those benefits than on medical/surgical benefits. The final rule applied mental health parity requirements to Medicaid Managed Care Organizations (MCOs), Section 1937 Alternative Benefit Plans (ABPs), and the CHIP.

The following four (4) provisions of the rule have collection of information requirements whose burden is discussed in section 12 of this Supporting Statement:

- *Medical Necessity Disclosure:* 42 CFR 438.915(a), 440.395(c)(1), and 457.496(e)(1) of the final rule require that the medical necessity determination criteria used by MCOs, PIHPs, and PAHPs or other utilization management organizations under contract with the state with respect to MH/SUD benefits be made available to potential participants, beneficiaries, or contracting providers upon request. CMS does not require that a specific form be used for these disclosures.
- *State Plan Amendments:* States with separate CHIPs need to submit a state plan amendment to indicate how they will comply with the requirements of §457.496. SPAs are submitted to OMB under control number 0938-1148 (CMS-10398).
- *Contract Requirements:* Section 438.3(n) requires states to include contract provisions in all applicable MCO, PIHP, and PAHP contracts to comply with the requirements of the final rule.
- *State Analysis and Transparency Responsibilities:* Section 438.920 specifies that in states where the full scope of services are not provided through the MCO, the state must review the benefits provided across delivery systems to ensure compliance. States are also required to review parity analyses provided by MCO that are responsible for delivering all services. The state must provide documentation of compliance with parity to the general public and post this information on the state’s Medicaid website.

The final rule also contains provisions related to the disclosure of information related to the reason for denial of reimbursement or payment for MH/SUD benefits. The final rule clarifies the

expectations for disclosing information concerning the denial of reimbursement or payment for MH/SUD benefits. It does not impose any new or revised third-party disclosure requirements.

In this 2025 iteration, we are adjusting our burden estimates based on more recent data. Overall, we estimate an increase of 46,494 responses and 7,656 hours. See section 15 of this Supporting Statement for details.

A. Justification

1. Need and Legal Basis

The 2016 final rule addressed the application of certain provisions added to the Public Health Service Act (PHS Act) (mental health parity requirements) by the provisions of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (Pub. L. 110–343) to: (1) Medicaid managed care organizations (MCOs) as described in section 1903(m) of the Act; (2) Medicaid benchmark and benchmark-equivalent plans (referred to in the rule as Medicaid Alternative Benefit Plans) as described in section 1937 of the Social Security Act (the Act); and (3) Children’s Health Insurance Program (CHIP) under title XXI of the Act.

Under section 1932(b)(8) of the Act, Medicaid managed care organizations (MCOs) are required to comply with the requirements of subpart 2 of part A of title XXVII of the PHS Act, to the same extent that those requirements apply to a health insurance issuer that offers group health insurance. Subpart 2 includes mental health parity requirements added by MHPAEA at section 2726 of the PHS Act (as renumbered; formerly section 2705 of the PHS Act). Under section 1937(b)(6) of the Act, Medicaid Alternative Benefit Plans (ABPs) that are not offered by an MCO and that provide both medical and surgical benefits and mental health and substance use disorder benefits are required to ensure that financial requirements and treatment limitations for such benefits comply with the mental health parity requirements of the PHS Act (referencing section 2705(a) of the PHS Act, which is now renumbered 2726(a) of the PHS Act), in the same manner as such requirements apply to a group health plan. The section 1937 provision applies only to ABPs that are not offered by MCOs; ABPs offered by MCOs are already required to comply with these requirements under section 1932(b)(8) of the Act. Section 2103(c)(7) of the Act requires that state CHIP plans that provide both medical and surgical benefits and mental health or substance use disorder benefits shall ensure that financial requirements and treatment limitations for such benefits comply with mental health parity requirements of the PHS Act (referencing section 2705(a) of the PHS Act, now renumbered as section 2726(a) of the PHS Act) to the same extent as such requirements apply to a group health plan. In addition, section 2103(f)(2) of the Act requires that CHIP benchmark or benchmark equivalent plans comply with all of the requirements of subpart 2 of part A of the title XXVII of the PHS Act, which includes the mental health parity requirements of the PHS Act, insofar as such requirements apply to health insurance issuers that offer group health insurance coverage.

2. Information Users

Medical Necessity Disclosure

Upon request, regulated entities must provide a medical necessity disclosure. Receiving this information will enable potential and current enrollees to make more educated decisions given the choices available to them through their plans and may result in better treatment of their MH/SUD conditions. MHPAEA also requires that plans and issuers provide the medical necessity disclosure to current and potential contracting health care providers. Because medically necessary criteria generally indicates appropriate treatment of certain illnesses in accordance with standards of good medical practice, this information should enable behavioral health practitioners and organizations to structure available resources to provide the most efficient health care for their patients.

State Plan Amendments

Information submitted to CMS regarding compliance of separate CHIP programs with MHPAEA requirements allows CMS to determine that states are fulfilling the requirements of the final rule.

Contract Requirements

States use the information collected and reported as part of its contracting process with managed care entities, as well as its compliance oversight role. CMS uses the information collected and reported in an oversight role of State Medicaid managed care programs.

State Analysis and Transparency Responsibilities

In states where an MCO is responsible for providing the full scope of medical/surgical and MH/SUD services to beneficiaries, the state reviews the parity analysis provided by the MCO to confirm that the MCO benefits are in compliance with the final rule.

In any instance where the full scope of medical/surgical and MH/SUD services are not provided through the MCO, the state must review the MH/SUD and medical/surgical benefits provided through the MCO, PIHP, PAHP, and fee-for service (FFS) coverage to ensure that the full scope of services available to all enrollees of the MCO complies with the requirements of this rule.

The state must provide documentation of compliance with the requirements under this subpart to the general public and post this information on the state's Medicaid website. This information allows members of the general public to see how the state is ensuring that its Medicaid and CHIP benefits are being provided in compliance with this rule.

3. Use of Information Technology

The 2016 final rule allows but does not require the use of information technology to fulfill the information collection requirements.

4. Duplication of Efforts

Because the 2016 rule was the first to extend mental health parity requirements to Medicaid and CHIP programs, no duplication of efforts are created by the information collection requirements of that rule or by this collection of information request.

5. Small Businesses

The 2016 final rule does not have a significant economic impact on a substantial number of small entities as that term is used in the RFA.

6. Less Frequent Collection

The frequency of disclosure of information regarding medical necessity depends on the number of enrollees who request such information, and is not at the discretion of CMS.

Contract amendments for MCOs, PIHPs, and PAHPs required by §438.3(n) are expected to be made one time only.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on September 25, 2025 (90 FR 46213). Comments were due by November 24, 2025. One comment was received but it is outside the scope of this parity package. Beneficiaries should contact their State Medicaid agency if they

require assistance in understanding written materials or to request translation.

The 30-day notice published in the Federal Register on December 22, 2025 (90 FR 59836). Comments must be received by January 21, 2026.

9. Payments/Gifts to Respondents

No payments or gifts are associated with this information collection request.

10. Confidentiality

Disclosures of medical necessity criteria require regulated entities to provide information to enrollees and contracting providers. Issues of confidentiality between third parties do not fall within the scope of this information collection request.

Information regarding state contracts with MCOs, PIHPs, and PAHPs is not confidential and its release would fall under the Freedom of Information Act.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Collection of Information Requirements and Associated Burden Estimates

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs, and our adjusted hourly wage.

Hourly Wage Estimates*				
Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operations Specialist	13-1000	43.76	43.76	87.52
Medical Secretaries and Administrative Assistants	43-6013	21.91	21.91	43.82

We have adjusted all our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary

significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Information Collection Requirements and Associated Burden Estimates

Availability of Information and the Criteria for Medical Necessity Determinations (Regulated Entities)

Sections 438.915(a), 440.395(c)(1), and 457.496(e)(1) require that the medical necessity determination criteria used by regulated entities with respect to MH/SUD benefits be made available to potential participants, beneficiaries, or contracting providers upon request.

In the November 13, 2013, MHPAEA final rule, the regulatory impact analysis (78 FR 68253 through 68266) quantified the costs to disclose medical necessity criteria. For consistency and comparability, we are using the same method for determining the rule's disclosure costs, with adjustments to account for Medicaid MCOs, ABP and CHIP and the population covered.

Labor-Related Burden for Medical Necessity Disclosures

We are unable to estimate with certainty the number of requests for medical necessity criteria disclosures that will be received by regulated entities. However, the 2013 MHPAEA final rule's impact analysis did set forth assumptions that we believe are relevant for calculating costs for the Medicaid and CHIP program. In that impact analysis, it was assumed that each plan would receive 3 medical necessity criteria disclosure requests for every 1,000 beneficiaries or 0.003 requests per enrollee. When applied to the number of enrollees enrolled in Medicaid we estimate 204,154 for MCOs (68.1 million MCOs x 0.003), 10,560 for ABPs (3.5 million ABP x 0.003) and 21,846 for CHIP (7.3 million CHIP x 0.003) for a total of 236,560 expected requests.

Consistent with the 2013 MHPAEA final rule, we estimate it takes 5 minutes (0.083 hr) at \$43.82/hr for a medical secretary to respond to each request. In aggregate, we estimate a burden of 19,713 hours (236,560 expected requests x 0.083 hr/request) at a cost of \$863,842 (19,713 hr x \$43.82/hr)

Labor-Related Burden for Medical Necessity Disclosures (Regulated Entities)

Plan Type	Number of Enrollees	Number of Expected Requests (0.003 requests per enrollee)	Total Time @ 5 min/response	Labor Cost (\$) @ \$43.82/hr	Mailed Responses (36% of expected requests)	Mailing and Supply Cost (\$) @ \$0.87/ mailing	Total Cost (\$)	State Costs (\$)
MCO/HIO	68,051,376	204,154	17,013 hr	745,503	n/a	n/a	745,503	279,340*
ABP	3,520,089	10,560	880 hr	38,563	n/a	n/a	38,563	14,450*
CHIP	7,282,155	21,846	1,821 hr	79,776	n/a	n/a	79,776	20,925**
<i>Subtotal: Labor</i>	<i>78,853,620</i>	<i>236,560</i>	<i>19,713 hr</i>	<i>863,842</i>	<i>n/a</i>	<i>n/a</i>	<i>863,842</i>	<i>314,715</i>

*The average Medicaid state share of the FY2022 Federal Medical Assistance Percentages (FMAP) is 37.47% (see November

30, 2020; 85 FR 76586).

** The average CHIP state share of the FY2022 Enhanced FMAP is 26.23% (see November 30, 2022; 85 FR 76586).

Non-Labor (Mailing and Supply) Costs for Medical Necessity Disclosures

The November 13, 2020 (85 FR 72754) Medicaid and CHIP managed care final rule (CMS-2408-F; RIN 0938–AT40) referenced research in the November 14, 2018 (83 FR 57278) Medicaid and CHIP managed care NPRM (CMS-2408-P, RIN 0938–AT40) that 64 percent of U.S. adults living in households with incomes less than \$30,000 a year owned smartphones in 2016, and lower income adults are more likely to rely on a smartphone for access to the internet because they are less likely to have an internet connection at home. We therefore believe it appropriate to estimate that 64 percent of the requests would be delivered electronically with de minimis cost. The remaining requests would require materials, printing, and postage amounting to approximately 87 cents per request. We believe that the same mailing and supply costs per request will apply to the disclosure requirements of the March 2016 final rule.

The following table displays the non-labor burden estimates, nationally and per program, for Medicaid MCOs and CHIP to comply with the medical necessity determination criteria's disclosure procedures. These estimates reflect the requests for medical necessity determination criteria's disclosure procedures by beneficiaries or contracting providers. The number of enrollees for MCOs/HIOs is based on 2024 CMS Medicaid managed care enrollment data while detailed information about enrollment in MCOs through ABPs isn't readily available to update this estimate from the last estimate. CHIP enrollment is based on April 2025 Medicaid & CHIP Enrollment Data.¹

Non-Labor (Mailing and Supply) Costs for Medical Necessity Disclosures (Regulated Entities)

Plan Type	Number of Enrollees	Number of Expected Requests (0.003 requests per enrollee)	Time @ 5 min/response	Labor Cost (\$) @ \$43.82/hr	Mailed Responses (36% of expected requests)	Mailing and Supply Cost (\$) @ \$0.87/ mailing	Total Cost (\$)	State Costs (\$)
MCO/HIO	68,051,376	204,154	n/a	n/a	73,495	63,941	63,941	23,959*
ABP	3,520,089	10,560	n/a	n/a	3,802	3,307	3,307	1,239*
CHIP	7,282,155	21,846	n/a	n/a	7,865	6,842	6,842	1,795**
<i>Subtotal: non-Labor</i>	<i>78,853,620</i>	<i>236,560</i>	<i>n/a</i>	<i>n/a</i>	<i>85,162</i>	<i>74,091</i>	<i>74,091</i>	<i>26,992</i>

*The average Medicaid state share of the FY2022 Federal Medical Assistance Percentages (FMAP) is 37.47% (see November 30, 2020; 85 FR 76586).

** The average CHIP state share of the FY2022 Enhanced FMAP is 26.23% (see November 30, 2022; 85 FR 76586).

Total Labor and non-Labor Burden for Medical Necessity Disclosures

¹ Estimates are based on the most recent data available at the time of the analysis.

**Total Burden: Availability of Information and the Criteria for Medical Necessity Determinations
(Regulated Entities)**

Plan Type	Number of Enrollees	Number of Expected Requests (0.003 requests per enrollee)	Time @ 5 min/response	Labor Cost (\$) @ \$43.82/hr	Mailed Responses (36% of expected requests)	Mailing and Supply Cost (\$) @ \$0.87/ mailing	Total Cost (\$)	State Costs (\$)
MCO/HIO	68,051,376	204,154	17,013 hr	745,503	73,495	63,941	809,444	303,299*
ABP	3,520,089	10,560	880 hr	38,563	3,802	3,307	41,870	15,689*
CHIP	7,282,155	21,846	1,821 hr	79,776	7,865	6,842	86,618	22,720**
TOTAL	78,853,620	236,560	19,713 hr	863,842	85,162	74,091	937,932	341,708

*The average Medicaid state share of the FY2022 Federal Medical Assistance Percentages (FMAP) is 37.47% (see November 30, 2020; 85 FR 76586).

** The average CHIP state share of the FY2022 Enhanced FMAP is 26.23% (see November 30, 2022; 85 FR 76586).

**Submitting Requests for Medical Necessity Disclosures
(Potential Participants, Beneficiaries, and Contracting Providers)**

The following table displays the revised burden estimates, nationally and per program, for Medicaid and CHIP potential participants, beneficiaries and providers to request the medical necessity determination criteria.

It is difficult to determine the financial impact on providers since the proportion of providers that would submit this request is unknown and the staff costs in these agencies would vary based on the level of professional (physician, licensed clinician, or medical claims staff) that may request this information.

Submitting Requests for Medical Necessity Disclosures (Potential Participants, Beneficiaries, and Contracting Providers)

Plan Type	Number of Enrollees	Number of Expected Requests (0.003 requests per enrollee)	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)	State Share (\$)
MCO/HIO	68,051,376	204,154	0.25	51,039	Unknown	Unknown	Unknown
ABP	3,520,089	10,560	0.25	2,640	Unknown	Unknown	Unknown
CHIP	7,282,155	21,846	0.25	5,461	Unknown	Unknown	Unknown
TOTAL	78,853,620	236,560	0.25	59,140	Unknown	Unknown	Unknown

State Contract Requirements

In §438.3(n), states are required to include contract provisions in all applicable MCO, PIHP, and PAHP contracts to comply with part 438, subpart K. We estimate a one-time state burden of 30 minutes for a Business Operations Specialist at \$87.52/hr to amend each contract with the applicable requirements. Since publication of the March 2016 final rule, most states have amended their existing contracts to include applicable language to comply with part 438, subpart

K. Therefore, we reduced our estimate to account for any contracts that still need to be amended or any new contracts that are found to be missing applicable federal requirements. In aggregate, we estimate 25 hours (50 contracts x 0.5 hr) and \$2,188 (25 hr x \$87.52/hr).

State Contract Requirements

Regulation Section(s) Under Title 42 of the CFR	Potential Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Hourly Labor Cost (\$/hr)	Total Labor Cost (\$)	Total Mailing and Supply Costs (\$)	Total Cost (\$)	State Share (\$)
438.3(n)	43 States	50	0.5	25	87.52	2,188	0	2,188	820*

*When considering our 37.47% state share estimate, state costs are estimated to be \$820.

State Analysis and Transparency Responsibilities

In any instance where the full scope of medical/surgical and MH/SUD services are not provided through the MCO, §438.920 specifies that the state must review the MH/SUD and medical/surgical benefits provided through the MCO, PIHP, PAHP, and fee-for service (FFS) coverage to ensure that the full scope of services available to all enrollees of the MCO complies with the requirements in subpart K. The state is also expected to review the parity analysis provided by an MCO that is responsible for delivering all MH/SUD Medicaid services. The state must provide documentation of compliance with the requirements under subpart K to the general public and post this information on the state's Medicaid website. The 43 states that have an MCO model would be responsible for developing or reviewing the benefits offered by MCOs, PIHPs, PAHPs and FFS to ensure the benefits offered to enrollees of the MCO comply with requirements in subpart K. Since publication of the March 2016 final rule, most states have developed or finished reviewing the MCO's initial parity analysis. We estimate a state burden of 4 hours at \$87.52/hour for a business operations specialist to finish reviewing the initial analysis and document compliance and, update the documentation when needed (i.e., re-procurement of MCOs, changes to benefits, etc.). In aggregate, we estimate 172 hours (43 states x 4 hr) and \$15,053 (172 hr x \$87.52/hr).

State Analysis and Transparency Responsibilities

Regulation Section(s) Under Title 42 of the CFR	Potential Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hours)	Hourly Labor Cost (\$/hr)	Total Labor Cost (\$)	Total Mailing and Supply Costs (\$)	Total Cost (\$)	State Share (\$)
438.920	43 States	43	4	172	87.52	15,053	0	15,053	5,641

*When considering our 37.47 % state share estimate, state costs are estimated to be \$5,641.

Summary of Annual Burden Estimates

Annual Recordkeeping and Reporting Requirements

Regulation Section(s) Under Title 42 of the CFR	Potential Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Hourly Labor Cost (\$/hr)	Total Labor Cost (\$)	Total Mailing and Supply Costs (\$)	Total Cost (\$)	State Share (\$)
438.915(a), 440.395(c) (1), and 457.496(e) (1) Availability of Information and the Criteria for Medical Necessity Determinations	602 Regulated Entities	236,560	0.0833 (5 min)	19,713	43.82	863,842	74,091	937,932 (863,842 + 74,091)	314,715 (labor) and 26,992 (non-labor)
Submitting Requests for Medical Necessity Disclosures	78,853,620 (Potential Participants, Beneficiaries, and Contracting Providers)	236,560 (78,853,620 * 0.003)	0.25	59,140	Unknown	Unknown	Unknown	Unknown	Unknown
438.3(n) State Contract Requirements	43 States	50	0.5	25	87.52	2,188	0	2,188	820
438.920 State Analysis and Transparency Responsibilities	43 States	43	4	172	87.52	15,053	0	15,053	5,641
TOTAL	78,854,308	473,213	Varies	79,050	Varies	1,744,925	74,091	955,174	348,168

*Total non-labor cost of \$74,091 with \$26,992 as the State share.

Collection of Information Guidance Forms and Instruction/Guidance Documents

Other than what has been promulgated in rulemaking or codified in the CFR, this collection of information request does not include any forms, guidance documents, or instructions.

13. Capital Costs

No capital costs are associated with this information collection request.

14. Cost to Federal Government

With a total estimated cost of \$955,174, the state share is estimated to be \$348,169 while the federal share is estimated at \$607,005 (see Section 12, above, under *Summary of Annual Burden Estimates*).

15. Changes to Burden

The increase in burden associated with the requirement that medical necessity determination criteria used by regulated entities with respect to MH/SUD benefits be made available to potential participants, beneficiaries, or contracting providers upon request (per §§ 438.915(a), 440.395(c)(1), and 457.496(e)(1)) is reflective of the growth in total Medicaid and CHIP enrollment since the publication of the 2016 final rule.

Labor Costs for Medical Necessity Disclosures: 438.915(a), 440.395(c)(1), and 457.496(e)(1) (Regulated entities)	Potential Respondents	Total Responses	Burden per Response	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$/hr)	Total Labor Cost of Reporting (\$)	Total Mailing and Supply Costs (\$)	Total Cost (\$)	State Share
Currently Approved 2022 Burden (Active)	602	213,314	5 min	17,776	38.22	679,406	66,810	746,216	270,03
2025 Burden	602	236,560	5 min	19,713	43.82	863,842	74,091	937,932	341,70
2025 Burden Adjustment	No Change	+23,246	No Changes	+1,937	+5.60	+184,436	+7,281	+191,716	+71,67

Submitting Requests for Medical Necessity Disclosures (Potential Participants, Beneficiaries, and Contracting Providers)	Potential Respondents	Total Responses	Burden per Response	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$/hr)	Total Labor Cost of Reporting (\$)	Total Mailing and Supply Costs (\$)	Total Cost (\$)	State Share
Currently Approved 2022 Burden (Active)	71,104,769	213,314	15 min	53,329	N/A	N/A	N/A	N/A	N/A
2025 Burden	78,853,620	236,560	15 min	59,140	N/A	N/A	N/A	N/A	N/A
2025 Burden Adjustment	+7,748,851	+23,246	No Changes	+5,811	N/A	N/A	N/A	N/A	N/A

The increase in burden associated with the contract requirements (per § 438.3(n)) and the state analysis and transparency requirements (per § 438.920) is due to an increase in the number of respondents. The remaining burden associated with § 438.3(n) accounts for MCO contracts that may need to be amended or any new contracts that are found to be missing applicable federal requirements. Since publication of the March 2016 final rule, seven additional states implemented managed care arrangements, bringing the total number of states with MCOs to 43. The remaining burden associated with § 438.920 reflects state and/or MCO efforts to document compliance and for updates to the documentation when needed (i.e., due to re-procurement of MCOs, changes to benefits, etc.).

Contract Requirements (§438.3(n))	Potential Respondents	Total Responses	Burden per Response	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$/hr)	Total Labor Cost of Reporting (\$)	Total Mailing and Supply Costs (\$)	Total Cost (\$)	State Share
Currently Approved (Active)	41	50	30 min	25	77.28	1,932	0	1,932	724
2025 Burden	43	50	30 min	25	87.52	2,188	0	2,188	820
2025 Burden Adjustment	+2	No Changes	No Changes	No Changes	+10.24	+256	No Changes	+256	+96

State Analysis and Transparency Responsibilities (\$438.920)	Potential Respondents	Total Responses	Burden per Response	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$/hr)	Total Labor Cost of Reporting (\$)	Total Mailing and Supply Costs (\$)	Total Cost (\$)	State Share
Currently Approved (Active)	41	41	4 hr	164	77.28	12,674	0	12,674	4,749
2025 Burden	43	43	4 hr	172	87.52	15,053	0	15,053	5,641
2025 Burden Adjustment	+2	+2	No Change	+8	+10.24	+2,379	No Change	+2,379	+892

Burden Reconciliation

Requirement	Potential Respondents	Total Responses	Burden per Response	Total Annual Burden (hours)	Hourly Labor Cost (\$/hr)	Total Labor Cost (\$)	Total Mailing and Supply Costs (\$)	Total Cost (\$)	State Share (\$)
Labor Costs for Medical Necessity Disclosures: 438.915(a), 440.395(c)(1), and 457.496(e) (1) (Regulated entities)	No Change	+23,246	No Change	+1,937	+5.60	+184,436	+7,281	+191,716	+71,673
Submitting Requests for Medical Necessity Disclosures (Potential Participants, Beneficiaries, and Contracting Providers)	+7,748,851	+23,246	No Change	+5,811	N/A	N/A	N/A	N/A	N/A
Contract Requirements (§438.3(n))	+2	No Change	No Change	No Change	+10.24	+256	No Change	+256	+96
State Analysis and Transparency Responsibilities (§438.920)	+2	+2	No Change	+8	+10.24	+2,379	No Change	+2,379	+892
Total 2025 Burden Adjustment	+7,748,855	+46,494	No Change	+7,756	+26.08	+187,071	+7,281	+194,351	+72,661

16. Publication/Tabulation Dates

No publication or tabulation dates are associated with this information collection request.

17. Expiration Date

The expiration date will be displayed.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

Not applicable. This information collection does not contain any questionnaires/surveys and does not employ any statistical methods.