

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 provisions of the rule have collection of information requirements:

- *Medical Necessity Disclosure*: Sections 438.915(a), 440.395(c)(1), and 457.496(e)(1) of this 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.
- *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 this 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 2022 iteration, we are adjusting our burden estimates based on more recent data. Overall, we estimate an increase of 14,367 responses, 2,398 hours, and \$18,635 (state share).

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

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

4. Duplication of Efforts

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

5. Small Businesses

This 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 7, 2022 (87 FR 54696). Comments must be received by November 7, 2022.

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

These ICRs involve no sensitive questions.

12. Collection of Information Requirements and Associated Burden Estimates

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 1 presents BLS' mean hourly wage, our cost of fringe benefits, and our adjusted hourly wage.

Table 1: Hourly Wage Estimates*

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operations Specialists	13-1000	38.64	38.64	77.28

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead ((\$/hr))	Adjusted Hourly Wage (\$/hr)
Medical Secretaries	43-6013	19.11	19.11	38.22

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 overhead 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.

12.2 Information Collection Requirements (ICRs) and Associated Burden

12.2.1 ICRs Regarding the Availability of Information and the Criteria for Medical Necessity Determinations (§§ 438.915(a), 440.395(c)(1), and 457.496(e)(1))

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 this rule's disclosure costs, with adjustments to account for Medicaid MCOs, ABP and CHIP and the population covered.

Labor Costs 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. This assumption equated to 0.003 requests per enrollee. This assumption was applied to the number of enrollees enrolled in Medicaid MCOs (58.5 million), ABP (3.5 million) and CHIP (9.1 million) to project the number of expected requests: 175,566 for MCOs, 10,560 for ABPs and 27,188 for CHIP.

To estimate the time it will take a medical staff to respond to each request we used the same assumption as the 2013 MHPAEA final rule. Specifically, we assumed that it took a staff member (in this case, a Medical Secretary) 5 minutes to respond to the request. This results in a total annual burden of 17,776 hours for Medicaid and CHIP programs.

The adjusted hourly rate for Medical Secretaries responding to these requests is estimated to be \$38.22/hr. Multiplying the total annual burden of 17,776 hours by the hourly wage yields an associated equivalent cost of about \$679,406 for all requests to Medicaid and CHIP programs.

Mailing and Supply Costs

The 2018 Medicaid and CHIP managed care NPRM referenced research (see 83 FR 57278) 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 this rule.

Table 2 displays the added 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 2017 CMS Medicaid managed care enrollment data while the number for ABPs is based on FY2017 Kaiser Family Foundation Medicaid expansion estimate and the 2017 CMS estimate of Medicaid enrollment in comprehensive MCOs under ACA Section VIII expansion. CHIP enrollment is based on FFY 2018 Statistical Enrollment Data System (SEDS) Reporting.¹

TABLE 2: National and Per Program Burden for the Medical Necessity Determination Criteria's Disclosure Requirements

Plan Type	Number of Enrollees	Number of Expected Requests (0.003 requests per enrollee)	Time (@ 5 min/ response)	Labor Cost (\$) @ \$38.22/hr	Mailed Responses (36 % of expected enrollees)	Mailing and Supply Cost (\$) @ \$0.87/ mailing	Total Cost (\$)	State Costs*
MCO/ HIO	58,521,930	175,566	14,630 hr	559,177	63,204	54,987	614,164	\$230,127
ABP	3,520,089	10,560	880 hr	33,634	3,802	3,307	36,941	\$14,961
CHIP	9,062,750	27,188	2,266 hr	86,595	9,788	8,515	95,110	\$24,947**
TOTAL	71,104,769	213,314	17,776 hr	679,406	76,793	66,810	746,216	\$270,035

*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)

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

Table 3 displays the added 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.

TABLE 3: National and Per Potential Participant, Beneficiaries and Provider Burden for the Medical Necessity Determination Criteria’s Disclosure Requirements

Plan Type	Number of Enrollees	Number of Expected Requests (0.003 requests per enrollee)	Time (@ 15 min/request)
MCO/ HIO	58,521,930	175,566	43,892 hrs.
ABP	3,520,089	10,560	2,640 hrs.
CHIP	9,062,750	27,188	6,797 hrs.
TOTAL	71,104,769	213,314	53,329 hrs.

12.2.2 ICRs Regarding Contract Requirements (§438.3(n))

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 \$77.28/hr to amend each contract with the applicable requirements. Since publication of the 2016 parity regulations, 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 hours) and \$1,932 (25 hours x \$77.28/hr). Taking into consideration our 37.47 % state share estimate, state costs are estimated to be \$724.

12.2.3 ICRs for State Analysis and Transparency Responsibilities (§438.920)

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 this 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 this subpart to the general public and post this information on the state’s Medicaid website. The 41 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 this subpart. Since publication of the final rule, most states have developed or

finished reviewing the MCO's initial parity analysis. We estimate a state burden of 4 hours at \$77.28/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 164 hours (41 states x 4 hours) and \$12,674 (164 hours x \$77.28/hr). Taking into consideration our 37.47 % state share estimate, state costs are estimated to be \$4,749.

12.3 Summary of Annual Burden Estimates

TABLE 4: Annual Recordkeeping and Reporting Requirements

Regulation Section(s) Under Title 42 of the CFR	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*
438.915(a), 440.395(c)(1), and 457.496(e)(1) (Regulated entities)	602	213,314	5 min	17,776	38.22	679,406	66,810	746,216	270,035
438.915(a), 440.395(c)(1), and 457.496(e)(1) (Potential participants, beneficiaries and providers)	71,104,769	213,314	15 min	53,329	N/A	N/A	N/A	N/A	N/A
438.3(n) (States)	41	50	30 min	25	77.28	1,932	0	1,932	724
438.920 (States)	41	41	4 hours	164	77.28	12,674	0	12,674	4,749
TOTAL	71,104,769	426,628	4 hrs. 50 min	71,294	--	694,012	66,810	760,822	275,508

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

13. Capital Costs

No capital costs are associated with this information collection request.

14. Cost to Federal Government

At 37.47 %, the state share is estimated to be \$275,508 while the federal share is estimated at \$484,314 (see Table 4, above).

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 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 2019 (Active)	602	206,131	5 min	17,178	35.66	612,567	64,560	677,127	251,551
2022 Burden	602	213,314	5 min	17,776	38.22	679,406	66,810	746,216	270,035
2022 Burden Adjustment	No Change	+7,183	No Change	+598	+2.56	+66,839	+2,250	+69,089	+18,484

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 2019 (Active)	68,710,529	206,131	15 min	51,533	N/A	N/A	N/A	N/A	N/A
2022 Burden	71,104,769	213,314	15 min	53,329	N/A	N/A	N/A	N/A	N/A
2022 Burden Adjustment	+2,394,240	+7,183	No Change	+1,796	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 an increase in the number of respondents. The remaining burden associated with § 438.3(n) accounts MCO contracts that still need to be amended or any new contracts that are found to be missing applicable federal requirements. Since publication of the 2016 final rule, 5 additional states implemented managed care arrangements, bringing the total number of states with MCOs to 41. The remaining burden associated with § 438.920 reflects state and/or MCO efforts to finish their initial analyses and 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 2019 (Active)	40	50	30 min	25	71.04	1,776	0	1,776	719
2022 Burden	41	50	30	25	77.28	1,932	0	1,932	724
2022 Burden Adjustment	+1	No Change	No Change	No Change	+6.24	+156	No Change	+156	+5

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 2019 (Active)	40	40	4 hr	160	71.04	11,366	0	11,366	4,603
2022 Burden	41	41	4 hr	164	77.28	12,674	0	12,674	4,749
2022 Burden Adjustment	+1	+1	No Change	+4	+3.66	+1,308	No Change	+1,308	+146

Burden Reconciliation

Requirement	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
Labor Costs for Medical Necessity Disclosures: 438.915(a), 440.395(c)(1), and 457.496(e)(1) (Regulated entities)	No Change	+7,183	No Change	+598	+2.56	+66,839	+2,250	+69,089	+18,484
Submitting Requests for Medical Necessity Disclosures (Potential Participants, Beneficiaries, and Contracting Providers)	+2,394,240	+7,183	No Change	+1,796	N/A	N/A	N/A	N/A	N/A
Contract Requirements (§438.3(n))	+1	No Change	No Change	No Change	+6.24	+156	No Change	+156	+5
State Analysis and Transparency Responsibilities (§438.920)	+1	+1	No Change	+4	+3.66	+1,308	No Change	+1,308	+146
Total 2022 Burden Adjustments	+2,394,242	+14,367	No Change	+2,398	+12.46	+68,303	+2,250	+70,553	+18,635

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.