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

This package is associated with our mental health parity final rule (CMS–2333–F; RIN 0938–AS24) which published in the Federal Register on March 30, 2016 (81 FR 18390).

Background

The current PRA submission relates to the 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" (see above for detailed citations). The final rule amends the Medicaid and CHIP regulations to implement the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). MHPAEA is a federal law 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 applies mental health parity requirements to Medicaid Managed Care Organizations (MCOs), Section 1937 Alternative Benefit Plans (ABPs), and the CHIP. Four provisions of the rule implicate PRA 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 is not requiring that a specific form be used for these disclosures.

- *State Plan Amendments*: States with separate CHIPs will need to submit a state plan amendment to indicate how they will comply with the requirements of §457.496. SPAs will be submitted to OMB under control number 0938-1148.

- *Contract Requirements*: Section 438.6(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 burden resulting from these requirements can be found in section 12 of this Supporting

Statement.

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 text only 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.

A. Justification

1. Need and Legal Basis

This final rule addresses 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)(6) 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 will allow 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 will review the parity analysis provided by the MCO to confirm that the MCO benefits are in compliance with this 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 will allow 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 will be created by the information collection requirements of this rule.

5. Small Businesses

This rule will 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 438.6(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

Serving as the 60-day notice, the NPRM published in the Federal Register on April 10, 2015 (80 FR 19418) (CMS-2333-P; RIN 0938-AS24). No further outside consultation was conducted. Public comment were received. A summary of the comments and our response is attached to this PRA package.

Of note, two commenters expressed concerns that the cost analysis of the proposed rule fails to consider the administrative cost to the states of creating new ongoing reporting mechanisms for states and MCOs to provide information on their quantitative and nonquantitative limits across multiple MCOs and the FFS structure, perform the parity analysis, post on the states website and report to CMS. In response, projections of this additional burden were added to the final rule and under ICRs for State Analysis and Transparency Responsibilities (§438.920) (see section 12.2.3, below).

The proposed rule did not set forth such burden since we requested comments on our proposed approach.

Additionally, based on internal review, the wage estimates from the proposed rule were revised to account for more recent BLS data. We also added burden for requesting the medical necessity determination criteria.

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. Burden Estimates (Hours & Wages)

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 1 presents the mean hourly wage,

the cost of fringe benefits, and the adjusted hourly wage.

Table 1: Hourly Wage Estimates*

Occupation Title	Occupation Code	Mean Hourly Wage	Fringe Benefit (at 100%)	Adjusted Hourly Wage
Business Operations Specialists	13-1000	$33.69/hr.	$33.69/hr.	$67.38/hr.
Medical Secretaries	43-6013	$16.12/hr.	$16.12/hr.	$32.24/hr.
Social Scientists and Related Workers	19-3099	$38.48/hr.	$38.48/hr.	$76.96/hr.

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, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

12.2 Information Collection Requirements (ICRs)

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 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 .003 requests per enrollee. This assumption was applied to the number of enrollees enrolled in Medicaid (33.1 million), ABP (8.7 million) and CHIP (5.7 million) to

project the number of expected requests: 99,328 for MCOs, 26,100 for ABPs and 16,975 for CHIP.

To estimate the time it will take a medical staff to respond to each request we used the same assumption as the 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 11,867 hours for Medicaid and CHIP programs.

The adjusted hourly rate for Medical Secretaries responding to these requests is estimated to be $32.24/hr. Multiplying the total annual burden of 11,867 hours by the hourly wage yields an associated equivalent cost of about $382,592 for all requests to Medicaid and CHIP programs.

Mailing and Supply Costs

The MHPAEA final rule's impact analysis estimated that 38 percent of the requests would be delivered electronically with de minimis cost. The remaining requests would require materials, printing, and postage amounting to approximately 66 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 the CMS national breakout as of July 2012 while the number for ABPs is based on the estimated enrollment growth due to Medicaid expansion ("National Health Expenditure Projections 2012–2022," CMS).[1] CHIP enrollment is based on Medicaid and CHIP Payment and Access Commission's 2014 estimates.

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 ($) @ $32.24/hr.	Mailed Responses (62 % of expected enrollees)	Mailing and Supply Cost ($) @ $0.66/ mailing	Total Cost ($)	State Costs*
MCO/ HIO	33,109,462	99,328	8,277 hr.	266,851	61,584	40,645	307,496	$117,464
ABP	8,700,000	26,100	2,175 hr.	70,122	16,182	10,680	80,802	$30,866
CHIP	5,658,460	16,975	1,415 hr.	45,620	10,525	6,947	52,567	$20,081
TOTAL	47,467,922	142,403	11,867 hr.	382,593	88,291	58,272	440,865	$168,411

*The average state share of total Medicaid spending is projected to be 38.2% (see mental health parity final rule (March 30, 2016; 81 FR 18435).

Submitting Requests for Medical Necessity Disclosures (Potential Participants, Beneficiaries,

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

and Contracting Providers)

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	33,109,462	99,328	24,832 hrs.
ABP	8,700,000	26,100	6,525 hrs.
CHIP	5,658,460	16,975	4,244 hrs.
TOTAL	47,467,922	142,403	35,601 hrs.

12.2.2 ICRs Regarding Contract Requirements (§438.6(n))

In §438.6(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 $67.38/hr to amend each contract with the applicable requirements. In aggregate, we estimate 301 hours (602 contracts x 0.5 hours) and $20,281 (301 hours x $67.38/hr). Taking into consideration our 38.2 % state share estimate, state costs are estimated to be $7,747.

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 36 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. We estimate a state burden of 8 hours at $67.38/hour for a business operations specialist to perform this analysis and document compliance and, on an ongoing basis, update the documentation. In aggregate, we estimate 288 hours (36 states x 8 hours) and

$19,405 (288 hours x $67.38/hr.). Taking into consideration our 38.2 % state share estimate, state costs are estimated to be $7,413.

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	142,403	5 min	11,867	32.24	382,592	58,272	440,865	168,411
438.915(a), 440.395(c)(1), and 457.496(e)(1) (Potential participants, beneficiaries and providers)	47,467,922	142,403	15 min	35,601	N/A	N/A	N/A	N/A	N/A
438.6(n) (States)	36	602	30 min	301	67.38	20,281	0	20,281	7,747
438.920 (States)	36	36	8 hours	288	67.38	19,405	0	19,405	7,413
TOTAL	47,468,596	285,444	8 hrs. 50 min	48,057	--	422,278	58,272	480,551	183,570

*The average state share of total Medicaid spending is projected to be 38.2%.

13. Capital Costs

No capital costs are associated with this information collection request.

14. Cost to Federal Government

At 38.2 %, the state share is estimated to be $183,570 while the federal share is estimated at $296,980 (see Table 4, above).

15. Changes to Burden

Not applicable. This is a new collection.

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.