



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 438, 440, 456, and 457

[CMS-2333-F]

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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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will address the application of certain requirements set forth in the Public Health Service Act, as amended by the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, to coverage offered by Medicaid managed care organizations, Medicaid Alternative Benefit Plans, and Children's Health Insurance Programs.

DATES: These regulations are effective on [Inset date 60 days after the date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT:

John O'Brien, (410) 786-5529, Alternative Benefit Plan.

Debra Dombrowski, (312) 353-1403, Managed Care.

Amy Lutzky, (410) 786-0721.

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Regulations Text

Acronyms, Abbreviations, and Short Forms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this final rule, we are listing the acronyms, abbreviation, and short forms used and their corresponding terms in alphabetical order below

| | |
|-------------------------|---|
| 2008 Extenders Act | Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Division C) |
| The Act | Social Security Act |
| The Affordable Care Act | Patient Protection and Affordable Care Act (Pub. L. 111-148, enacted on March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) |
| The Departments | Departments of the Treasury, Labor, and Health and Human |

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| | Services |
| ABP | Alternative Benefit Plan |
| BBA | Balanced Budget Act of 1997 |
| CHIP | Children's Health Insurance Program |
| CHIPRA | Children's Health Insurance Program Reauthorization Act of 2009 |
| CMS | Centers for Medicare and Medicaid Services |
| The Code | Internal Revenue Code of 1986 |
| DOL | Department of Labor |
| DSM | Diagnostic and Statistical Manual of Mental Disorders (current edition) |
| EHB | Essential Health Benefit |
| EPSDT | Early and Periodic Screening, Diagnostic and Treatment |
| ERISA | Employee Retirement Income Security Act of 1974 |
| FFP | Federal Financial Participation |
| FFS | Fee for Service |
| HHS | Department of Health and Human Services |
| ICD | International Classification of Diseases |
| MCE | Managed Care Entity |
| MCO | Managed Care Organization |
| MH | Mental Health |
| MH/SUD | Mental Health or Substance Use Disorder |
| MHPA | Mental Health Parity Act of 1996 |
| MHPAEA | Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 |

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| NQTL | Nonquantitative Treatment Limitation |
| PAHP | Prepaid Ambulatory Health Plan |
| PHS Act | Public Health Service Act |
| PIHP | Prepaid Inpatient Health Plan |
| SHO | State Health Official |
| SUD | Substance Use Disorder |
| Treasury | Department of the Treasury |

I. Executive Summary

This final rule addresses the application to Medicaid and the Children's Health Insurance Program (CHIP) of certain mental health parity requirements added to the Public Health Service Act (PHS Act) by the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (Pub. L. 110–343, enacted on October 3, 2008). Specifically, this final rule addresses the application of MHPAEA parity requirements to: (1) Medicaid managed care organizations (MCOs) as described in section 1903(m) of the Social Security Act (the Act); (2) Medicaid benchmark and benchmark-equivalent plans (referred to in this rule as Medicaid Alternative Benefit Plans (ABPs)) as described in section 1937 of 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 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 that are now found 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 ABPs that are not offered by an MCO and that provide both medical and surgical benefits and mental health or substance use disorder

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(MH/SUD) 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 (renumbered section 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 MH/SUD benefits shall ensure that financial requirements and treatment limitations for such benefits comply with mental health parity requirements of the PHS Act (referencing renumbered 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.

These final rules incorporate these requirements into our regulations.

II. Background

A. Legislative History

On September 26, 1996, the Congress enacted the Mental Health Parity Act of 1996 (Pub. L. 104-204) (MHPA), which required parity in aggregate lifetime and annual dollar limits for mental health benefits and medical/surgical benefits. Those mental health parity provisions were codified in section 712 of ERISA, section 2726 of the PHS Act (renumbered under section 1001 of the Affordable Care Act), and section 9812 of the Code, and applied to employment-related group health plans and health insurance coverage offered in connection with a group

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health plan. The Balanced Budget Act of 1997 (Pub. L. 105-33, enacted on August 5, 1997) (BBA) added sections 1932(b)(8) and 2103(f)(2) of the Act to generally apply certain aspects of MHPA, including the provisions of section 2726 of the PHS Act, to Medicaid MCOs and CHIP benefits.

MHPAEA was enacted as sections 511 and 512 of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Division C of Pub. L. 110-343) (the 2008 Extenders Act). MHPAEA amended the Employee Retirement Income Security Act of 1974 (ERISA), the PHS Act, and the Internal Revenue Code of 1986 (the Code). The changes made by MHPAEA consist of new standards, including parity for coverage of substance use disorder benefits, as well as amendments to the existing mental health parity provisions enacted in MHPA.

In 2009, section 502 of the Children's Health Insurance Program Reauthorization Act of 2009 (Pub. L. 111-3) (CHIPRA) amended section 2103(c) of the Act by adding paragraph (6), which requires that CHIP plans that provide both medical and surgical benefits and MH/SUD benefits comply with the provisions of section 2705(a) of the PHS Act, as amended by MHPAEA, in the same manner as a group health plan.

The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010 and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) was enacted on March 30, 2010 (collectively referred to as the "Affordable Care Act"). Section 1001 of the Affordable Care Act reorganized and renumbered certain provisions of the PHS Act, including renumbering section 2705 of the PHS Act as section 2726 of the PHS Act. The Affordable Care Act did not make conforming changes to cross-references to the renumbered provisions; instead, it contained new cross-references to the former section numbers. However, there was no indication that Congress intended to alter the meaning of the existing cross-references. As a result, we read the cross-references to continue to refer to the same section

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originally referenced, as renumbered. We believe it is clear that the new cross-references were also intended to refer to the renumbered provisions.

The Affordable Care Act expanded the application of section 2705(a) of the PHS Act, as amended by MHPAEA, and renumbered as section 2726(a) of the PHS Act, to benefits in Medicaid ABPs delivered outside of a MCO. ABPs delivered through an MCO would already have to comply with these requirements under section 1932(b)(8) of the Act. Also, section 2001(c) of the Affordable Care Act modified the benefit provisions of section 1937 of the Act. Specifically, section 2001(c) of the Affordable Care Act added mental health benefits and prescription drug coverage to the list of benefits that must be included in benchmark-equivalent coverage; required the inclusion of essential health benefits (EHBs) beginning in 2014; and directed that plans described in section 1937 of the Act (now known as ABPs) that include medical/surgical benefits and MH/SUD benefits ensure that the financial requirements and treatment limitations applicable to such MH/SUD benefits comply with the mental health parity provisions of the PHS Act.

The Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively the Departments) published interim final regulations implementing MHPAEA on February 2, 2010 (75 FR 5410), and final regulations applicable to group health plans and health insurance issuers on November 13, 2013 (78 FR 68240) (MHPAEA final regulations).¹ The MHPAEA final regulations do not apply to Medicaid MCOs, ABPs, or CHIP state plans.

¹ The MHPAEA final regulations generally apply to group health plans and health insurance issuers on the first day of the first plan year beginning on or after July 1, 2014. The preamble to the MHPAEA final regulations stated that each plan or issuer subject to the interim final regulations, issued on February 2, 2010 (75 FR 5410), must continue to comply with the applicable provisions of the interim final regulations until the corresponding provisions of these final regulations become applicable to that plan or issuer (78 FR 68252 and 253). Note: for ease of reference, the citations to provisions of the MHPAEA final rules throughout this document will only refer to the provisions adopted by HHS in 45 CFR part 146.

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In 2013, we released a State Health Official (SHO) letter that provided guidance to states regarding the implementation of requirements under MHPAEA to Medicaid benchmark and benchmark-equivalent plans (referred to in the letter as ABPs) as described in section 1937 of the Act, CHIP under title XXI of the Act, and MCOs as described in section 1903(m) of the Act.² We previously issued a SHO letter on November 4, 2009, concerning the application of section 502 of CHIPRA.³

In April 2015, we published a proposed rule on the 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 ABPs (80 FR 19418-19452). In this rule, we are finalizing regulations to address how the MHPAEA requirements in section 2726 of the PHS Act, as implemented in the MHPAEA final regulations, apply to MCOs, ABPs, and CHIP. For a more detailed description of the proposed provisions, please refer to the proposed rule (80 FR 19418).

B. Stakeholder Input

We received a total of 158 comments from state agencies, advocacy groups, health care providers, health insurers, health care associations, and the general public. The comments ranged from general support or opposition (to various provisions in the proposed rule) to very specific questions or comments regarding the proposed changes. After consideration of the comments and feedback received from stakeholders, we are adopting these final regulations. The following are brief summaries of each proposed provision, a summary of public comments received, and our responses to the comments. Comments related to the paperwork burden and

² <http://www.medicaid.gov/federal-policy-guidance/downloads/sho-13-001.pdf>

³ <http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO110409.pdf>

the impact analyses are addressed in the “Collection of Information Requirements” and “Regulatory Impact Analysis” sections in this preamble.

III. Provisions of the Final Rule and Analysis of and Responses to Public Comments

The provisions of this final rule generally mirror the policies set forth in the MHPAEA final regulations to implement the statutory provisions that require MCOs, ABPs and CHIP to comply with certain requirements of section 2726 of the PHS Act (mental health parity requirements).

The following sections, arranged by subject area, include a summary of the public comments that we received, and our responses.

A. Definitions (§438.900, §440.395, §457.496)

The definitions of terms in the proposed rule and in this final rule include most terms included in the MHPAEA final regulation at 45 CFR 146.136(a). The proposed rule modified or added several terms to reflect the terminology used in the Medicaid program and CHIP statutes, regulations or policies. Some terms that are not relevant to the Medicaid program or CHIP were not included in the proposed rule. There were also several proposed terms that modified, added or deleted language from those definitions in the MHPAEA final regulations. For example:

- We proposed to add the terms ABP and Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits since these terms are unique to the Medicaid program.
- We proposed to add the definition of “essential health benefits”, since Medicaid benchmark and benchmark-equivalent plans (now also known as ABPs) must cover EHBs and MH/SUD services provided as an EHB must be compliant with parity.
- We proposed a different definition for the term “medical/surgical benefits,” to reflect that the state defines these benefits in the Medicaid and CHIP contexts. Under existing law, the state has the responsibility of identifying what is a covered benefit for Medicaid and CHIP;

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MCOs, PIHPs or PAHPs are responsible for providing the covered benefits identified by the state. This is different from the MHPAEA final regulations, where medical/surgical benefits are defined under the terms of the group health plan or health insurance coverage and in accordance with applicable federal or state law.

- We also proposed that the definitions of “medical/surgical benefits,” “mental health benefits,” and “substance use disorder benefits” would clearly exclude long term care services in the Medicaid and CHIP context. We stated that this clarification was consistent with the intent of the MHPAEA final regulations, given that the kinds of long term care services included in benefit packages for Medicaid and CHIP beneficiaries were not commonly provided in the commercial market as part of health benefits coverage. We sought comments on our proposal to exclude long term care services from the definitions of “medical/surgical benefits,” “mental health benefits,” and “substance use disorder benefits.”

Comment: We received many comments on the proposal to exclude long term care services from the definitions of “medical/surgical benefits,” “mental health benefits,” and “substance use disorder benefits.” A few commenters supported the proposal to exclude long term care services from the definitions of “medical/surgical benefits,” “mental health benefits,” and “substance use disorder benefits” as used in this rule. The commenters requested that additional guidance regarding the definition of long term care services be provided to ensure consistency in states’ and plans’ parity analyses.

However, a large majority of commenters opposed this approach, and recommended that the final rule apply parity protections to long term MH/SUD benefits. Commenters who opposed the proposed rule approach provided three general concerns. First, many commenters noted that Medicaid is the nation’s largest provider of benefits coverage for individuals with MH/SUD conditions and the only benefits coverage for most disabled individuals with these conditions;

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these commenters stated that parity protections in Medicaid should be at least as strong as the rules governing the commercial market. The commenters also discussed the importance of access to long term care services for the effective treatment of many MH/SUD conditions, particularly within the populations served by Medicaid and CHIP programs.

Second, several commenters noted that commercial plans typically do cover some forms of long term care services for both MH/SUD and medical/surgical conditions, including skilled nursing, inpatient rehabilitation, and home health services. From this perspective, commenters stated that CMS is prohibited from excluding the application of parity to long term care services because section 1932(b)(8) of the Act requires Medicaid MCOs to comply with the requirements of MHPAEA “to the same extent that those requirements apply to a health insurance issuer that offers group health insurance.” Underlying this claim from commenters is the view that commercial insurers of group health plans would be obligated to meet parity requirements in connection with coverage of long term care services in order to comply with PHS Act section 2726. To the extent that Medicaid coverage does differ from the commercial market, commenters stated that the regulations must reflect the differences between commercial insurance and Medicaid and CHIP, as well as the different needs of the populations that each type of health coverage serves. These commenters stated that the proposed rule's approach misconstrues the intent and substance of the parity requirements if parity requirements only apply to Medicaid and CHIP services that are also covered by commercial insurance. Commenters suggested that there is no statutory basis for the interpretation underlying the proposed rule on this point and the corresponding application that long term services be excluded from the parity analysis. Commenters also stated that there are many services covered in the commercial plans that are comparable to long term services covered by Medicaid such as personal care, where the services might be covered for medical-surgical conditions, but not for

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MH/SUD because they are defined as “long term care.” This opens the door for decisions to exclude coverage or impose different financial or treatment limitations that would be otherwise prohibited by this rule but are wholly justified on any plausible rationale that characterizes the services as long term care.

Third, and finally, many commenters also identified the difficulty of formulating clear and consistent standards to distinguish between long term care services and other services across treatment settings, from both a definitional and an operational perspective; they stated that it would be administratively difficult to implement a policy that carved these services out of medical, surgical, MH/SUD benefits to exclude long term care services from parity protections. Many commenters also raised concerns that adopting this exclusion without providing a regulatory definition of long term care services would allow states and plans to declare a number of services to be long term care and thus not subject to parity in an inconsistent manner. Having no consistent definition of long term service would create disparate policies across states as to which services would not be subject to parity and therefore would have allowable quantitative and nonquantitative treatment limits on services that were needed on a long term basis. In addition, some services that may be currently considered intermediate and subject to parity may be intentionally classified by states or MCOs, PIHPs or PAHPs to be long term services and excluded from parity. Commenters stated that if all long term care services are excluded from parity protections, MCOs, PIHPs and PAHPs may financially benefit from the anticipated cost savings of shifting away from acute care to long term care and have no obligation to ensure that there is mental health parity within long term care benefits. This may also preclude any systematic basis to audit MCOs, PIHPs or PAHPs compliance with relevant MHPAEA requirements applied to long term services.

For these reasons, most commenters requested that parity requirements under this final

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rule be applied to long term care services that are within the scope of medical/surgical or mental health/substance use disorder services, or that if the exclusion were to be maintained, that very clear definitions and guidelines be provided regarding the services to be characterized as long term care services that are excluded from these other classification of services set forth in this rule.

Response: We agree with the commenters and have revised this final rule to include long term care services in the definitions of medical/surgical, mental health, and substance use disorder benefits, and, thus, to apply parity protections under this final rule to long term care services. Therefore, long term care services will need to be included in the appropriate classification(s) of benefits provided for in this rule for the purposes of the parity analysis. We intend to provide additional information to states regarding the application of parity to long term services. This information will assist states in determining how various medical/surgical and MH/SUD long term services would be classified in the four areas (inpatient, outpatient, pharmacy and emergency).

We believe this change will reduce the likelihood that states would have disparate policies regarding which services would be subject to parity and could ensure that beneficiaries have similar protections regardless of where they live. In addition, this prevents states from applying treatment limits to long term care services needed for MH/SUD conditions more restrictively than treatment limits are applied for long term care services for medical/surgical conditions. We also believe that by requiring the categorization of long term services used to treat MH/SUD conditions, this final rule could improve beneficiary access to needed MH/SUD benefits. Finally, finalizing the regulations in this final rule with this change will provide MCOs and states with needed clarity regarding the application of parity to these services.

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Comment: Many commenters supported the guidance provided in the proposed rule regarding state-defined MH/SUD benefits. Commenters noted that requiring state definitions to be consistent with generally recognized independent standards of current medical practice will help ensure Medicaid managed care beneficiaries receive clinically appropriate levels of care. However, several commenters offered specific recommendations regarding the scope of definitions for medical/surgical services and MH/SUD services in the proposed rule. For instance, one commenter recommended that CMS define the scope of MH/SUD to be consistent with the psychiatric diagnoses listed in the new DSM-5 and in the Diagnostic Classification of Mental Health and Developmental Disorders Infancy and Early Childhood. Several commenters also cautioned that Medicaid's medical/surgical benefits should be defined specifically for the child and adolescent population to ensure consistent implementation.

Several other commenters recommended that CMS provide a non-exhaustive list of "mental health conditions" that must be included within a state's definition of "mental health condition". They added that simply stating that this term must be defined consistent with generally recognized independent standards of medical practice does not provide sufficient clarity and guidance to states. Commenters suggested that a non-exhaustive list would give greater clarity and uniformity among states, thus facilitating the collection and analysis of data and outcomes measures.

Response: We believe that requiring states to include specific diagnosis or providing a non-exhaustive list of mental health conditions in a state's definition of mental health conditions is beyond the scope of this regulation and CMS authority. Since Medicaid is a state and federal partnership, we believe that the state, and not CMS, should identify which conditions are considered medical/surgical and MH/SUD conditions. Therefore, we do not provide a list (either exhaustive or non-exhaustive) of mental health conditions in this final rule. The language in the

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final regulation provides states guidance regarding generally recognized independent standards of current medical practice to determine what conditions are medical/surgical, mental health, and substance use disorders.

Comment: One commenter suggested that CMS should clarify that quantitative visit limits do not apply to required services such as services provided by clinical psychologists and clinical social workers in FQHCs.

Response: We believe that the current regulation provides sufficient information regarding the application of parity standards to treatment limits imposed on MH/SUD services. To the extent permissible under existing law, states and MCOs may impose quantitative treatment limits for MH/SUD benefits, so long as these limits are no more restrictive than the predominant limits applied to substantially all medical/surgical benefits in each classification; if existing law prohibits the imposition of any treatment limitation on a service covered by a Medicaid or CHIP state plan, this rule does not provide authority to impose such limits merely because parity standards would be met. This rule allows states to apply quantitative treatment limits, consistent with other law, to services regardless of the type of practitioner that renders either a medical/surgical service or MH/SUD service so long as the parity requirements are met. A discussion of the mandatory coverage requirements for Medicaid and CHIP is otherwise outside the scope of this final rule.

Comment: Another commenter recommended that CMS should clarify that utilization management and prior authorization or concurrent review can function as “soft limits” that allow for an individual to exceed medical/surgical or MH/SUD benefit limits based on medical necessity.

Response: We are clarifying in this final rule that benefit limits that allow for an individual to exceed numerical limits for medical/surgical or MH/SUD benefits based on medical

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necessity are not considered to be quantitative treatment limits under this rule, but are subject to the provisions of this rule governing Nonquantitative Treatment Limitations (NQTLs) for medical/surgical or MH/SUD benefits. The processes, strategies, evidentiary standards, or other considerations that are used to determine whether to apply a soft limit must be comparable to and applied no more stringently than factors used in applying the limitation for medical surgical/benefits in the classification.

Comment: Another commenter suggested that CMS include a list of terms that have different meanings in Medicaid and commercial plans and clarify how these meanings apply in the context of parity protections provided in Medicaid and the commercial market.

Response: We appreciate the commenter's suggestion. However, we believe that we provide adequate discussion of the similarities and differences in the use of terms in Medicaid and commercial plans in the text of this regulation and other regulations governing Medicaid, CHIP and the commercial health insurance market.

For the reasons described in the proposed rule and in consideration of the comments received, we are finalizing the provisions proposed in §438.900, §440.395, and §457.496 of the proposed rule with modification. We are finalizing revised definitions of medical/surgical, mental health, and substance use disorder services so that they include, rather than exclude, long term care services. Additional modifications to the definitions proposed in §457.496 are discussed in section III.G of this final rule.

B. Parity Requirements for Aggregate Lifetime and Annual Dollar Limits (§438.905 and §457.496(c))

In proposed §438.905 and §457.496(c), we addressed the parity requirements for aggregate lifetime and annual dollar limits for MCOs (including PIHPs and PAHPs when providing coverage for MCO enrollees) and CHIP. As noted above, the application of these

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requirements under this rule is generally the same as under the MHPAEA final regulations (45 CFR 146.136(b)). If a regulated entity applies an aggregate lifetime or annual dollar limit to at least two-thirds of all medical/surgical benefits, it must either apply the aggregate limit to both to medical/surgical benefits and to MH/SUD benefits in a manner that does not distinguish between the medical/surgical and MH/SUD benefits, or not include an aggregate lifetime or annual dollar limit on MH/SUD benefits that is less than the aggregate limit on medical/surgical benefits. If a regulated entity does not include an aggregate lifetime or annual dollar limit on medical/surgical benefits or includes a limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on MH/SUD benefits. If a regulated entity applies an aggregate lifetime or annual dollar limit to between one-third and two-thirds of all medical/surgical benefits, it must either impose no aggregate lifetime or annual dollar limit on MH/SUD benefits, or impose an aggregate lifetime or annual dollar limit on MH/SUD benefits that is no more restrictive than the average limit for medical/surgical benefits. These requirements do not address the provisions of section 2711 of the PHS Act, which prohibit imposing lifetime and annual limits on the dollar value of essential health benefits.

We noted in the proposed rule that for managed care arrangements, we are using our authority in section 1902(a)(4) of the Act to require PIHPs and PAHPs to comply with mental health parity requirements when providing coverage for MCO enrollees. The proposed regulations included definitions of “aggregate lifetime dollar limit” and “annual dollar limit” at §438.900, §440.395(a), and §457.496(a).

Comment: One commenter suggested that CMS should consider including a definition of “coverage unit” that mirrors the definitions in the MHPAEA final regulations.

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Response: We did not include a definition of coverage unit in this rule because in Medicaid and CHIP programs, the coverage unit will always be the individual beneficiary, regardless of marital or family status.

Comment: Another commenter requested that CMS provide clarification on the use of aggregate lifetime and annual dollar limits in the context of section 2711 of the PHS Act, as added by section 1001 of the Affordable Care Act, which generally prohibits lifetime and annual limits on the dollar amount of EHB, including MH/SUD services.

Response: Section 2711 of the PHS Act, as added by the Affordable Care Act, generally prohibits lifetime and annual limits on the dollar amount of EHB in group health plans and health insurance coverage. As set forth in section 1302(b) of the Affordable Care Act, the definition of EHB includes “mental health and substance use disorder services, including behavioral health treatment.”⁴ Thus, notwithstanding the provisions of MHPAEA that permit aggregate lifetime and annual dollar limits with respect to MH/SUD benefits as long as those limits are in accordance with the parity requirements for such limits, such dollar limits are prohibited with respect to MH/SUD benefits that are covered as EHB, regardless of the service delivery system within Medicaid Alternative Benefit Plans.

Section 2711 of the PHS Act is applied to Medicaid MCOs by section 1932(b)(8) of the Act and to CHIP benchmark or benchmark-equivalent plans by section 2103(f)(2) of the Act (as section 2711 is part of subpart 2 of part A of title XXVII of the PHS Act). ABP and CHIP benefits that are offered through an MCO, or through a PIHP or PAHP that provides coverage to MCO enrollees are also subject to the prohibition on lifetime and annual limits. However, the prohibition on annual and lifetime limits in section 2711 of the PHSA does not apply to ABPs that are not offered by an MCO or by a PIHP, or PAHP to enrollees of an MCO.

⁴ See section 1302(b)(1)(E) of the Affordable Care Act.

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Regardless of whether services are delivered in managed care or non-managed care arrangements, all Medicaid ABPs (including benchmark equivalent and Secretary–approved benchmark plans) and CHIP plans are statutorily required by sections 1937(b)(6) and 2103(c)(6) of the Act to meet the financial requirements and treatment limitations components of the mental health parity provisions set forth at section 2726(a) of the PHS Act.

Comment: One commenter indicated that CMS should consider the extent to which §438.905 appears to sanction aggregate lifetime or annual dollar limits in the Medicaid program. For example, paragraph (c) discusses a Medicaid MCO with an annual or lifetime dollar limit on two-thirds of all medical and surgical benefits. The commenter further states that it is difficult to imagine how a lifetime limit on two-thirds of all medical and surgical benefits would meet the sufficiency, access and comparability requirements of Medicaid.

Response: This final rule neither sanctions nor prohibits aggregate lifetime and annual dollar limits; this rule merely provides the standards for applying parity requirements to such limits if the limits are otherwise authorized. While we agree that a lifetime limit on two-thirds of all medical and surgical benefits would not likely meet the sufficiency, access, and comparability requirements of Medicaid, sufficiency, access, and comparability requirements are outside of the scope of this final rule.

Comment: One commenter noted that the use of the phrase “in states that cover both medical and surgical benefits and mental health and substance use disorder benefits under their State plan” is not necessary. All state Medicaid programs contain at least some mental health and SUD benefits, because hospital and physician services are mandatory benefits that include mental health and SUD treatment.

Response: We agree that inpatient hospital and physician services are mandatory state plan services that furnish services to address MH/SUD. However, as noted, under section

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1932(b)(8) of the Act, Medicaid MCOs are required to comply with mental health parity requirements in section 2726 of the PHS Act to the same extent that those requirements apply to a health insurance issuer that offers group health insurance. The parity requirements in section 2726 of the PHS Act are limited to group health plans or health insurance issuers offering group or individual health insurance coverage that provides both medical and surgical benefits and MH/SUD benefits. Similarly, section 2103(c)(6) of the Act requires that state CHIP plans that provide both medical and surgical benefits and MH/SUD benefits shall ensure that financial requirements and treatment limitations for such benefits comply with mental health parity requirements of section 2726(a) of the PHS Act to the same extent as such requirements apply to a group health plan. Therefore, we are retaining the clarifying language in §§438.905(a), 438.910(b), 457.496(d)(2), and 457.496(f) of this final rule that these requirements apply to states that offer both medical and surgical and MH/SUD benefits.

We are finalizing the provisions at §§ 438.905 and 457.496(c) about aggregate lifetime and annual limits for Medicaid MCOs and CHIP as proposed. In the proposed rule, we included under §438.905 the title of “General” under paragraph (a), with paragraph of “General parity requirement” under (a)(1). As we do not intend to use paragraph (a)(2), in the final rule we have removed the paragraph numbering for (a)(1) and named “General parity requirement” simply under paragraph (a) of this section, rather than including “General” in the title.

C. Parity Requirements for Financial Requirements and Treatment Limitations (§§438.910, 440.395(b), and 457.496(d))

Sections 438.910, 440.395(b), and 457.496(d) of the proposed rule set forth parity requirements for financial requirements and treatment limitations.

1. Clarification of Terms

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In the proposed rule, we indicated that “classification of benefits” means a classification as described in §438.910, §440.395(b), and §457.496(d), which describe parity requirements for financial requirements and treatment limitations. Specifically, we proposed to modify the classifications of benefits set forth in the regulations that were adopted by the Departments in the 2010 MHPAEA final rule (as discussed in section III.C.2). As in the MHPAEA final regulations, we proposed in this Medicaid and CHIP rule that parity requirements for financial requirements and treatment limitations be applied on a classification by classification basis.

We proposed the term “type” to refer to financial requirements and treatment limitations of the same nature. Different types of financial requirements and treatment limitations include copayments, coinsurance, annual visit limits, and episode visit limits. We proposed that a financial requirement or treatment limitation must be compared only to financial requirements or treatment limitations of the same type within a classification.

In addition, we proposed the term “level” to refer to the magnitude (such as the dollar, percentage, day, or visit amount) of the financial requirement or treatment limitation. We did not receive any comments on the definitions of terms described at §438.910, §440.395(b), and §457.496(d) and are finalizing these terms as proposed.

2. General Parity Requirement for Financial Requirements and Treatment Limitations

At proposed §438.910(b), §440.395(b)(2), and §457.496(d)(2), we included general parity provisions to prohibit a MCO, PIHP or PAHP (when providing benefits to an MCO enrollee), ABP (when used in a non-managed care arrangement), or CHIP state plan from applying any financial requirement or treatment limitation to MH/SUD benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type that is applied to substantially all medical/surgical benefits in the same classification. For this purpose, the general parity requirement of MHPAEA would apply

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separately for each type of financial requirement or treatment limitation (for example, unit limits are compared to unit limits, or co-pays are compared to co-pays).

We noted in the proposed rule that the MHPAEA final regulations at §146.136(c)(2)(ii) set forth the following classifications of benefits: inpatient in-network; inpatient out-of-network; outpatient in-network; outpatient out-of-network; emergency care; and prescription drugs. We proposed to follow the general structure of the classifications used in the MHPAEA final regulations with a significant distinction. Specifically, we proposed to eliminate the in-network and out-of-network distinctions for the inpatient and outpatient classifications, and therefore to provide four classifications: inpatient; outpatient; emergency care; and prescription drugs.

As discussed in this final rule, we maintain this classification structure. The four classifications in this final rule are the only classifications to be used for purposes of applying the parity requirements of MHPAEA to Medicaid and CHIP. Moreover, these classifications must be used for all financial requirements and treatment limitations to the extent that a MCO, PIHP, PAHP, ABP, or CHIP provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification. Similar to the MHPAEA final rule, this final rule does not define what services are included in the inpatient, outpatient, or emergency care classifications. These terms are subject to the design of a state's managed care program and their meanings may differ depending on the benefit packages.

For the purposes of applying parity requirements to Medicaid, we proposed that the classifications of benefits should relate to how states construct and manage their Medicaid benefits. All Medicaid benefits provided should fall into one of the classifications of benefits. We noted that the MHPAEA final regulations discussed the application of parity requirements to intermediate services (such as residential treatment, partial hospitalization, and intensive

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outpatient treatment) provided under the health plan. Specifically, the MHPAEA final regulations required group health plans and issuers to assign covered intermediate MH/SUD benefits to a benefit classification in the same manner that they assign comparable intermediate medical/surgical benefits to a classification. The MHPAEA final regulations do not specifically define intermediate services; nor do current statutory and regulatory provisions governing the Medicaid and CHIP programs define intermediate services within state plan benefits. Therefore, we did not propose to specify an intermediate classification to be used in the parity analysis for Medicaid or CHIP programs. As in the MHPAEA final rule, we proposed to allow the applicable regulated entity (the MCO, PIHP or PAHP, or state in connection with the ABP, and CHIP) to assign intermediate level services to any of the classifications listed, but require that assignment to those classifications be done using the same standards for both medical/surgical services and MH/SUD services (see §438.910(b)(2), §440.395(b)(2)(ii), and §457.496(d)(2)(ii)). This final rule also requires that the method used to assign services to the four classifications be reasonable.

We note that similar concerns may arise regarding the classification of long term care services, given the revised definitions of mental health benefits and substance use disorder benefits set forth in this final rule. We did not propose and do not finalize any specific rules for the classification of long term care services. This final rule allows the applicable regulated entity (the MCO, PIHP or PAHP, or state in connection with the ABP, a carve-out managed care delivery system, and CHIP) to assign long term care services to any of the four listed classifications, but, as with intermediate and other services, requires that assignment to those classifications be done using the same reasonable standards for both medical/surgical services and MH/SUD services.

Comment: Many commenters provided feedback on this approach. Some commenters

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requested that CMS create a new intermediate level services classification and clarify that intermediate services for MH/SUD must be covered if similar types of services are covered for medical/surgical conditions. However, most commenters supported the consistency of the proposed approach with the MHPAEA final rules, and appreciated that this approach would give some flexibility to states and health plans to assign intermediate level services to the four classifications in the proposed rule. Commenters noted that consistency with the MHPAEA final rules would make it easier for states and plans to comply. Since other aspects of the benefit, including financial requirements and NQTLs, are influenced by the classification a service is put into, this flexibility would allow states and plans to determine the most appropriate classification for intermediate services based on the entire benefit package that is offered.

Response: Similar to the MHPAEA final rule, this final rule does not define what services are included in the inpatient, outpatient, or emergency care classifications. Similar to the reasoning provided in the MHPAEA final regulations, we did not intend to impose a benefit mandate through the parity requirement in order to require greater benefits for mental health conditions and substance use disorders than for medical/surgical conditions. In addition, as noted above, current statutory and regulatory provisions governing the Medicaid and CHIP programs do not define intermediate services within state plan benefits. The definitions of the four classifications used by this rule are subject to the design of a state's managed care program, and their meanings may differ depending on the benefit packages. State health insurance laws may define these terms, and in the event that these are not defined, we expect each regulated entity within a state to define these classifications in a similar manner. Further, each regulated managed care plan (MCOs, PIHPs and PAHPs) or the state in connection with ABP, or CHIP, must apply these terms uniformly for both medical/surgical benefits and MH/SUD benefits under §438.910(b)(2), §440.395(b)(2)(ii) and §457.496(d)(2)(ii). Therefore, we are not including a

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new intermediate level services classification in this final rule.

Comment: Some commenters requested that the final rule clearly state that intermediate services offered in Medicaid and CHIP are subject to the parity requirements. The commenters urged CMS to provide guidance regarding MH/SUD intermediate care services and provide examples and resources that mirror the provisions included in the MHPAEA final rule. Many commenters also requested guidance on the types of factors and processes that should be used to classify intermediate care services into the benefit classifications for parity assessments to ensure consistency across payers in the application of parity to these services. Many commenters requested additional examples of intermediate services that can be classified as inpatient or outpatient. Commenters expressed particular concern about the need to define intermediate services clearly if long term care services were excluded from the final rule. Given the similarities and overlap between many intermediate services and long term care services, commenters expressed concern that plans would be able to classify services as long term care and exclude them from parity protections.

Response: We reiterate that all Medicaid services provided should be placed into one of the classifications of benefits for the purposes of this final rule. This final rule does not provide any authority for a medical/surgical or mental health/substance use disorder benefit to be classified or characterized as something other than the four classifications in §438.910(b)(2), §440.395(b)(2)(ii) and §457.496(d)(2)(ii). In addition, as noted in section III.A, this final rule includes long term care services in the definitions of “medical/surgical benefits,” “mental health benefits,” and “substance use disorder benefits.” Therefore, the distinction between intermediate services and long term care services is not material to the application or enforcement of this final rule. However, we have amended the provisions at §§438.910(b)(2), 440.395(b)(2)(ii) and 457.496(d)(2)(ii) to note that the factors used to classify services in the four classifications must

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be reasonable in addition to being the same for medical/surgical and MH/SUD services. We believe that this reasonableness requirement should help to allay concerns that services could be classified according to arbitrary factors in an attempt to permit the application of discriminatory limitations to MH/SUD services under this rule.

Comment: One commenter emphasized the difficulty of ensuring parity requirements across delivery platforms, especially as they relate to NQTLs and intermediate services. The commenter noted that the line between intermediate services and long term care services is not always clear, and stated that medical necessity criteria would need to be established to differentiate levels of care within long term care services. The commenter requested additional guidance on how to address parity requirements for services that are unique to Medicaid and for which comparable services on the medical/surgical side do not exist.

Response: As noted above, this final rule applies parity requirements to all intermediate and long term care services. Medical necessity determinations for long term care services or other services are an NQTL that must comply with the requirements of this rule. The parity analysis does not require a one-to-one comparison of a MH/SUD service to a medical/surgical service, but instead requires that a NQTL may not be imposed for a MH/SUD benefit in any classification unless, under the terms of the coverage, as written and in operation, any factors used in applying the NQTL to the MH/SUD benefit are comparable to and applied no more stringently than factors used in applying the same NQTL to medical/surgical benefits in the classification; we address NQTL standards in greater detail in section F. If questions persist regarding the development and use of medical necessity criteria under this rule, and/or methodologies for classifying intermediate and long term care services into the four benefit classifications provided in this rule, we may develop further guidance or provide technical assistance as needed.

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Comment: One commenter requested guidance to the states on developing clinically appropriate intensity of service and licensure expectations of facilities that provide behavioral health services which are not readily classifiable.

Response: This final rule clarifies that mental health parity requirements under this final rule do not apply to state licensure laws, and therefore such guidance is beyond the scope of this final regulation. Clinical determinations regarding medical necessity, such as the intensity of services that is medically necessary for an individual, are subject to the NQTL requirements set forth in this final rule. In addition, any processes, strategies, evidentiary standards, or other considerations that are used to guide clinical determinations concerning the appropriate intensity of service are also subject to the NQTL requirements set forth in this final rule.

As indicated in the responses to comments, we are finalizing these provisions mostly as proposed. We are finalizing §§438.910(b)(2), 440.395(b)(2)(ii) and 457.496(d)(2)(ii) with a modification that requires that the standards used to assign benefits to a classification be reasonable as well as the same for both medical/surgical and MH/SUD benefits.

3. Applying the general parity requirement to financial requirements and quantitative treatment limitations (§§438.910(c), 440.395(b)(3), and 457.496(d)(3)).

At proposed §§438.910(c), 440.395(b)(3) and, 457.496(d)(3), we addressed the application of the general parity requirement of MHPAEA to financial requirements and quantitative treatment limitations in MCOs, PIHPs, PAHPs, ABP and CHIP state plans. The general parity requirement at proposed §§438.910(b), 440.395(b)(2), and 457.496(d)(2) and now finalized in this rule would prohibit a MCO, PIHP or PAHP (in connection with coverage provided to an MCO enrollee), or ABP state plan (when used in a non-managed care arrangement), or CHIP state plan or MCE contracting with a CHIP state plan from applying any financial requirement or treatment limitation to MH/SUD benefits in any classification that is

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more restrictive than the “predominant” financial requirement or treatment limitation of that type applied to “substantially all” medical/surgical benefits in the same classification. In the proposed regulation text (that is, §§438.910(c), 440.395(b)(3) and 457.496(d)(3)), we proposed standards that are the same as those in the MHPAEA final regulations for determining the portion of medical/surgical benefits subject to a financial requirement or quantitative treatment limitation for purposes of the parity analysis. Under the proposed and now final rule, the portion of medical/surgical benefits in a classification subject to a financial requirement or quantitative treatment limitation would be based on the dollar amount of all payments for medical/surgical benefits in the classification expected to be paid during a specific year. For MCOs, PIHPS and PAHPs, this means dollar amounts for payment during a contract year. For ABPs and CHIP state plans, this means dollar amounts for the year starting the effective date of the approved ABP or CHIP state plan; effective dates for these plans will vary based on the date the ABP or CHIP state plan was approved by CMS. For purposes of this calculation, the MCOs (when such organizations are responsible for coverage of MH/SUD benefits) or the state (in cases where PIHPs and PAHPs are used in conjunction with MCOs) must determine the total amount projected to be expended to determine the two-thirds threshold.

We included a detailed example to illustrate how our proposal would work:

Example. Facts. A state is providing a comprehensive service package through an MCO. The MCO is currently providing coverage of services with limits that are consistent with the approved state plan. The MCO benefit package includes:

- Inpatient Hospital services for medical/surgical – 30 days per year limit.
- Inpatient Hospital services for MH/SUD – 30 days per year limit.
- Primary Care Physician Services for medical/surgical – unlimited.
- Specialist Physician Services for medical/surgical – 50 visits per year.

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- Outpatient MH services – 20 visits per year limit.
- Physical Therapy – 20 visits per year limit.
- Occupational Therapy – 20 visits per year limit.
- Emergency Services – Unlimited for medical/surgical or MH/SUD

The MCO projects its payments as follows for medical/surgical benefits:

TABLE 1: Example of Quantitative Treatment Limit

| Benefit/classification – Medical/Surgical | Projected Payment | Percent of total costs | Percent of classification subject to a limit |
|--|--------------------------|-------------------------------|---|
| Inpatient Hospital | \$400x | 100% | 100% |
| Inpatient total | \$400x | 100% | 100% |
| Physician Services | \$150x | 27% | 0% |
| Specialist Services | \$250x | 46% | 46% |
| Physical Therapy | \$75x | 13.5% | 13.5% |
| Occupational Therapy | \$75x | 13.5% | 13.5% |
| Outpatient total | \$550x | 100% | 73% |
| Emergency Services | \$100x | 100% | 0% |
| Emergency total | \$100x | 100% | 0% |

Example . Conclusion. In this example, the MCO would be able to maintain some level of day and visit limits on benefits in both the inpatient and outpatient MH/SUD classifications because both classifications meet the “substantially all” standard—in other words, more than two-thirds of the medical/surgical benefits in each classification are subject to those types of limits (100 percent of all medical/surgical inpatient benefits are subject to a day limit, and 73 percent of all medical/surgical outpatient benefits are subject to a visit limit).

With regards to the level of the quantitative treatment limitation on inpatient MH/SUD services, the MCO may maintain its 30 day limit because 100 percent of all inpatient medical/surgical benefits are also subject to a 30 day limit, making it the predominant level.

However, with regards to the level of the quantitative treatment limitation on outpatient MH/SUD services, the MCO may not maintain its current limit of 20 visits per year. Of the total amount of outpatient medical/surgical benefits subject to a visit limit (\$400x), 62.5 percent

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(\$250x) are subject to a 50 visit limit (specialist services), and only 37.5 percent (\$150x) are subject to a 20 visit limit (physical therapy and occupational therapy). Because the 20 visit limitation is not the predominant level (that is, it does not apply to at least 50 percent of the medical/surgical benefits in the classification subject to the visit limit), the MCO would need to either remove the visit limits altogether on outpatient MH/SUD services or increase the visit limitation to at least 50 visits per year to align with the least restrictive level of visit limits on outpatient medical/surgical benefits. Lastly, because there are currently unlimited emergency visits under the medical/surgical benefits, the MCO would need to maintain unlimited visits for emergency services for MH/SUD, and would not be able to impose any limits on MH/SUD unless limits were also imposed on medical/surgical services and such limits were consistent with parity requirements.

We received no comments on applying the general parity requirement to financial requirements and quantitative treatment limitations as described in §§438.910(c), 440.395(b)(3), and 457.496(d)(3). We are finalizing these provisions as proposed.

4. Special Rules for Multi-Tiered Prescription Drug Benefits and Other Benefits

(§§438.910(c)(2), 440.395(b)(3)(ii), 457.496(d)(3)(ii))

The MHPAEA final regulations at 45 CFR 146.136(c)(3)(iii)(A) permit plans under certain circumstances to apply different levels of financial requirements to different tiers of prescription drugs and still satisfy the parity requirements. The proposed rule would allow a MCO, PIHP, PAHP, ABP, or CHIP state plan to subdivide the prescription drug classification into tiers based on reasonable factors as described in the proposed regulations and without regard to whether a drug is generally prescribed for medical/surgical benefits or for MH/SUD benefits.

The MHPAEA final regulations at 45 CFR 146.136(c)(3)(iii)(C) permit a subclassification for office visits, separate from other outpatient items and services. Other

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subclassifications not specifically permitted, such as separate sub-classifications for generalists and specialists, cannot be used for purposes of determining parity. As proposed and finalized in this rule, we will retain this approach to subclassifications in the application of these parity requirements established in parts 438, 440 and 457 (that is, to services provided to enrollees in Medicaid MCOs, and to ABPs and CHIP). After the subclassification is established, a MCO, PIHP, PAHP, ABP, or CHIP state plan may not impose any financial requirement or quantitative treatment limitation on MH/SUD benefits in any sub-classification (for example, office visits or non-office visits) that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification, using the parity analysis for financial requirements and quantitative treatment limitations.

In the MHPAEA final regulations, the Departments recognized that tiered provider networks have become an important tool for health plan efforts to manage care and control costs. Therefore, for purposes of applying the financial requirement and treatment limitation rules under MHPAEA, the MHPAEA final regulations provide that if a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers in any classification), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect those network tiers, if the tiering is done without regard to whether a provider is a MH/SUD provider or a medical/surgical provider. While network tiers may also be used in Medicaid managed care, we do not believe that the parity standards for Medicaid managed care need to address such network structures so we did not propose regulation text to address financial limitations (for example, different cost-sharing requirements) in that context in this rule. Medicaid cost-sharing rules

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apply regardless of network status. Any quantitative treatment limitation outlined in the contract must be applied to the service broadly and therefore cannot have separate limitations based on network tiers. We recognize there may be network tiers used to commonly refer enrollees or for purposes of building the network and have varying payment rates to providers, but the use of multiple network tiers in the context of NQTLs is discussed in section III.E. of this final rule.

Comment: One commenter stated that network adequacy provisions in §438.206 are not specific enough and encouraged CMS to provide more specificity in the number, types of providers that must be in network, as well as time and distance requirements in current Medicaid managed care regulations.

Response: We believe that providing standards that specify the number and types of providers that must be in the network is beyond the scope of this rule. These standards are addressed in existing regulations at §438.206 and §438.2075. The parity proposed rule stated that a plan complying with the network adequacy requirements of §438.206(b)(4) will be deemed in compliance with §438.910(d)(3). In this final rule we removed the provision to deem compliance with §§438.910(d)(3) and 457.496(d)(5) of this rule (regarding parity requirements for access to out-of-network providers) where an MCO, PIHP, PAHP, or CHIP state plan is found to be in compliance with the provider network standard found in §438.206(b)(4).

As indicated in the responses to the comments, we are finalizing the provisions regarding multi-tiered prescription drug benefits and other benefits at §§438.910(c)(2), 440.395(b)(3)(ii), 457.496(d)(3)(ii) as proposed.

D. Cumulative Financial Requirements (§438.910(c)(3), §440.395(b)(3)(iii),

§457.496(d)(3)(iii))

⁵ We note that CMS proposed changes to §§438.206 and 438.207 that we believe are consistent with the intent of these final rules in CMS-2390-P Medicaid and CHIP Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability.

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While financial requirements such as copayments and coinsurance generally apply separately to each covered expense, other financial requirements (in particular, deductibles) accumulate across covered expenses. In the case of deductibles, generally an amount of otherwise covered expenses must be accumulated before the plan pays benefits. Financial requirements that determine whether and to what extent benefits are provided based on accumulated amounts were defined in the proposed rules as cumulative financial requirements. As in the MHPAEA final rule at §146.136(c)(v), we proposed and are finalizing in this final rule that separate cumulative financial requirements (separate for mental health, substance use or medical/surgical) will not be permitted for entities subject to our proposed requirements (namely, MCOs, PIHPs and PAHPs in connection with coverage provided to MCO enrollees, and in ABP and CHIP).

However, unlike the MHPAEA final rule for insurers of group health plans, in the Medicaid and CHIP proposed rule we proposed to permit quantitative treatment limitations to accumulate separately for medical/surgical and MH/SUD services as long as they comply with the general parity requirement. We proposed to allow this separate accumulation of treatment limits in Medicaid and CHIP for several reasons. First, benefits for MCO beneficiaries must be provided in at least the same amount, duration, and scope as set forth in the state plan. Requiring plans to have cumulative limits across medical/surgical benefits and MH/SUD benefits within a classification may incentivize MCOs to retain the quantitative treatment limitation level applied on the medical/surgical benefits in the state plan as the total cumulative limit for both medical/surgical and MH/SUD benefits. This would comply with the requirements of parity, but would not meet the requirements of providing at least what is in the state plan. In addition, we believe that requiring quantitative treatment limitations within a classification of benefits to accumulate jointly toward a unified limit level may not benefit the enrollee. Specifically, if there

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were a combined visit or treatment limit individuals that have co-occurring disorders may not be able to use the same level of MH/SUD services they would have been able to use if benefits accumulated separately. In recognition of the positive beneficiary impact, we proposed and are finalizing in this rule to permit the MCO, PIHP, or PAHP to maintain separate quantitative treatment limitations, provided that any such limit for MH/SUD benefits is no more restrictive than the predominant limit applied to substantially all medical/surgical benefits in a given classification.

However, as noted in this section, to align with the MHPAEA final regulations, we are retaining the proposal that separate cumulative financial requirements will not be permitted. This is because we also believe that a unified cumulative deductible is also more beneficial for the beneficiary and is in recognition that Medicaid programs generally do not have financial requirements that are cumulative, such as deductibles, and that financial requirements such as co-pays, which are common in Medicaid programs, do not typically include cumulative limits. While we recognize the potential for ABPs to include deductibles, we note that nearly all group health plans and insurers had eliminated the use of separate deductibles for MH/SUD benefits by 2011.⁶

Comment: A few commenters supported the proposal to follow the general approach in the MHPAEA final rule, but to allow entities subject to our proposed requirements to maintain separate accumulation of quantitative treatment limits. Commenters noted that unified quantitative treatment limitations that accumulate across entities would be very difficult for Medicaid managed care plans to administer, particularly if they do not have contractual

⁶ Final Report: Consistency of Large Employer and Group Health Plan Benefits with Requirements of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. NORC at the University of Chicago for the Office of the Assistant Secretary for Planning and Evaluation. This study analyzed information on large group health plan benefit designs from 2009 through 2011 in several databases maintained by benefits consulting firms that advise plans on compliance with MHPAEA as well as other requirements.

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relationships with other entities, and also supported that view that this provision is necessary to address the complex health needs of Medicaid and CHIP populations.

Response: We appreciate the comments in support of our approach.

As indicated in the response to comments, we are finalizing §§438.910(c)(3), 440.395(b)(3)(iii), 457.496(d)(3)(iii) as proposed.

E. Compliance with Other Cost-sharing Rules (§438.910(c)(4))

States and the MCOs, PIHPs and PAHPs that contract with states are bound by the existing Medicaid and CHIP cost-sharing rules (§438.108 and part 457, subpart E). As previously indicated, the Medicaid program and CHIP are held to strict cost-sharing requirements for both managed care and non-managed care delivery systems. In the proposed rule, we emphasized that all financial requirements included in a MHPAEA analysis must also be in compliance with both existing cost-sharing rules and the requirements of this rule. Compliance with the parity requirements does not mean that a state, or MCO, PIHP or PAHP can violate existing cost-sharing requirements. Therefore, some cost-sharing structures in a state's Medicaid program or CHIP may need to change to be compliant with the MHPAEA parity standards addressed in this rule. To clarify this, in §438.910(c)(4) we reiterated that requirement with a cross-reference to the cost-sharing rules applicable to MCOs, PIHPs and PAHPs.

We received no comments on this specific proposal and are finalizing §438.910(c)(4) as proposed.

F. Nonquantitative Treatment Limitations (NQTLS) (§438.910(d), §440.395(b)(4), and §457.496(d)(4) and (d)(5))

MCOs, PIHPs, PAHPs, ABP and CHIP state plans may impose a variety of limits affecting the scope or duration of benefits that are not expressed numerically. Nonetheless, such nonquantitative provisions are also treatment limitations affecting the scope or duration of

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benefits. As proposed and now finalized, §§438.910(d), 440.395(b)(4), and 457.496(d)(4) prohibit the imposition of any nonquantitative treatment limitation (NQTL) to MH/SUD benefits unless certain requirements are met. In addition, the proposed provisions and this final rule provide an illustrative list of NQTLs, including medical management standards; prescription drug formulary design; standards for provider admission to participate in a network; and conditioning benefits on completion of a course of treatment.

Under the MHPAEA final regulations at §146.136(c)(4), a NQTL may not be imposed for MH/SUD benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any factors used in applying the NQTL to MH/SUD benefits in a classification are comparable to and applied no more stringently than factors used in applying the limitation for medical surgical/benefits in the classification. For these purposes, factors mean the processes, strategies, evidentiary standards, or other considerations used in determining limitations on coverage of services.

We proposed to adopt the same approach to NQTLs in the application of parity requirements to Medicaid MCOs, PIHPs and PAHPs providing services to MCO enrollees, ABPs, and CHIP state plans. For states that are using a non-managed care delivery system for their ABPs and CHIP, the state (through its ABP and CHIP state plan) may only impose a NQTL on a MH/SUD benefit in any classification if it has written and operable processes, strategies, evidentiary standards or other factors used in applying -- to MH/SUD benefits in that classification -- the NQTL that are comparable to or less restrictive and applied no more stringently than any processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical services in that classification. The phrase “applied no more stringently” requires that any processes, strategies, evidentiary standards, or other

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factors that are comparable on their face be applied in the same manner to medical/surgical benefits and MH/SUD benefits.

We proposed and are finalizing in this rule an example of an NQTL regarding standards for accessing out-of-network providers. As discussed earlier, in the context of CHIP or ABPs that use a FFS delivery system or other non-managed care arrangement, absent a waiver, beneficiaries may choose from any qualified provider that has signed a Medicaid or CHIP provider agreement and are not limited to a network. In a Medicaid managed care environment, if a provider network is unable to provide necessary services covered under the contract to a particular enrollee, the MCO, PIHP or PAHP must adequately (and on a timely basis) cover these services out-of-network for the enrollee for as long as the MCO, PIHP or PAHP is unable to provide them in-network.⁷ The proposed rule specified that the standard for providing access to out-of-network services (when they cannot be provided in-network) is considered to be an NQTL for the purposes of this rule. The proposed regulation stated that regulated entities providing access to out-of-network providers for medical/surgical benefits within a classification must use the same processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for MH/SUD benefits within the same classification. As discussed further, we are revising the proposed regulation in this final rule for consistency with the general NQTL standard, to require that the factors used in determining access to out-of-network providers for MH/SUD benefits be comparable to and applied no more stringently than the factors used in determining access to out-of-network providers for medical/surgical benefits in the classification, rather than requiring that the same factors be applied to both sets of benefits.

Finally, the proposed rule provided that if MCOs, PIHPs or PAHPs, ABPs and CHIP State plans provided through managed care are found to be in compliance with §438.206(b)(4),

⁷ See §438.206(b)(4).

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that would be evidence that they are in compliance with §438.910(d)(3) and §457.496(d)(5), although the state will want to review how the plan is doing this in practice. We noted that the additional example of a NQTL regarding out-of-network providers is not relevant for states that are using a non-managed care delivery system for ABPs and CHIP state plan, since providers must be enrolled in Medicaid or CHIP and would not be considered out-of-network. As discussed below, we are not finalizing this approach to deemed compliance in this final rule in §§438.910(d)(3) and 457.496(d)(5), and instead are clarifying that regulated entities must comply with both sets of requirements.

We included in the proposed rule the examples, which have been modified slightly for greater clarity below, to illustrate the operation of the requirements for NQTLs.

Example 1. Facts. A MCO requires prior authorization that a treatment is medically necessary for all inpatient medical/surgical benefits and for all inpatient MH/SUD benefits. In practice, inpatient benefits for medical/surgical conditions are routinely approved for 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the MCO. Conversely, for inpatient MH/SUD benefits, routine approval is given only for 1 day, after which a treatment plan must be submitted by the beneficiary's attending provider and approved by the MCO.

Example 1. Conclusion. In this example, the MCO violates the NQTL provision of this rule (§438.910(d)) because it is applying a stricter NQTL in practice to MH/SUD benefits than is applied to medical/surgical benefits.

Example 2. Facts. A MCO applies concurrent review to inpatient care where there are high levels of variation in length of stay (as measured by a coefficient of variation exceeding 0.8). In practice, the application of this standard affects 60 percent of MH/SUDs, but only 30 percent of medical/surgical conditions.

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Example 2. Conclusion. In this example, the MCO complies with the NQTL provisions of this rule because the evidentiary standard used by the MCO is applied no more stringently for MH/SUD benefits than for medical/surgical benefits, even though it results in an overall difference in the application of concurrent review for MH/SUDs than for medical/surgical conditions.

Example 3. Facts. A MCO requires prior approval that a course of treatment is medically necessary for outpatient medical/surgical and MH/SUD benefits and uses comparable criteria in determining whether a course of treatment is medically necessary. For MH/SUD treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, providers will only receive a 25 percent reduction in payments for these treatments from the MCO.

Example 3. Conclusion. In this example, the MCO violates the NQTL provision of this rule. Although the same NQTL – medical necessity – is applied both to MH/SUD benefits and to medical/surgical benefits for outpatient services, it is not applied in a comparable way. The penalty for failure to obtain prior approval for MH/SUD benefits is not comparable to the penalty for failure to obtain prior approval for medical/surgical benefits.

Example 4. Facts. A MCO generally covers medically appropriate treatments. For both medical/surgical benefits and MH/SUD benefits, evidentiary standards used in determining whether a treatment is medically appropriate are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that is based on clinically appropriate standards of care for a condition.

Example 4. Conclusion. In this example, the MCO complies with the NQTL provision of the rule because the processes for developing the evidentiary standards used to determine

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medical appropriateness and the application of these standards to MH/SUD benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for MH/SUDs as it does for any particular medical/surgical condition, so long as the outcomes are the result of consistent application of the guidelines.

Example 5. Facts. Training and state licensing requirements often vary among types of providers. An MCO applies a general standard that any provider must meet the minimum requirement related to supervised clinical experience under applicable state licensure laws to participate in the MCO's provider network. State law requires master's level general medical providers to have post-degree, supervised clinical experience; therefore the MCO requires all master's level providers in its network (including mental health providers) to have post-degree, supervised clinical experience. State law does not require master's level mental health therapists to have post-degree, supervised clinical experience; therefore the MCO requirement to participate in the network is effectively higher than state law for master's level mental health therapists.

Example 5. Conclusion. In this example, the MCO complies with the provision of this rule pertaining to NQTLs. The requirement that all master's-level providers (including mental health providers) must have supervised post-degree supervised clinical experience to join the network is permissible because the MCO is consistently applying the same standard to all providers, even though it may have a disparate impact on certain mental health providers.

Example 6. Facts. A state contracts with an external utilization review entity to review inpatient admissions for all beneficiaries participating in its ABP. All inpatient services in the ABP are delivered on a FFS basis. The state's utilization review contractor considers a wide

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array of factors in designing medical management techniques for both MH/SUD and medical/surgical inpatient benefits, such as cost of treatment; high cost growth; variability in cost and quality; elasticity of demand; provider discretion in determining diagnosis, or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; and claim types with a high percentage of fraud. Based on application of these factors in a comparable fashion, prior authorization is required for some (but not all) inpatient MH/SUD benefits, as well as for some (but not all) medical/surgical benefits. The evidence considered in developing its medical management techniques includes consideration of a wide array of recognized medical literature and professional standards and protocols (including comparative effectiveness studies and clinical trials). This evidence and how it was used to develop these medical management techniques is also well documented by the state's utilization review organization.

Example 6. Conclusion. In this example, the state and its utilization review contractor comply with the NQTL rules. Under the terms of the ABP as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the contractor in implementing the prior authorization requirement for MH/SUD inpatient benefits are comparable to, and applied no more stringently than, those applied to medical/surgical benefits.

Example 7. Facts. A MCO provides coverage for medically appropriate medical/surgical benefits, as well as MH/SUD benefits. The MCO excludes coverage for inpatient SUD services when obtained outside of the state. There is no similar exclusion for medical/surgical benefits within the same classification.

Example 7. Conclusion. In this example, the MCO violates the NQTL provisions of this rule. The MCO is imposing a NQTL that restricts benefits based on geographic location.

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Because there is no comparable exclusion that applies to medical/surgical benefits, this exclusion may not be applied to MH/SUD benefits.

Example 8. Facts. A state's CHIP program requires prior authorization for all outpatient MH/SUD services after the ninth visit and will only approve up to 5 additional visits per authorization. For outpatient medical/surgical benefits, the state's CHIP program allows an initial visit without prior authorization. After the initial visit, benefits must be pre-approved based on the individual treatment plan recommended by the attending provider based on that individual's specific medical condition. There is no explicit, predetermined cap on the amount of additional visits approved per authorization.

Example 8. Conclusion. In this example, the state's CHIP program violates the NQTL provisions of the rule. Although the same NQTL – prior authorization to determine medical appropriateness – is applied to both MH/SUD benefits and medical/surgical benefits for outpatient services, it is not applied in a comparable way. While the state CHIP plan is more generous in the number of visits initially provided without pre-authorization for MH/SUD benefits, treating all MH/SUDs in the same manner, while providing for individualized treatment of medical conditions, is not a comparable application of this NQTL.

Example 9. Facts. A state provides an ABP that is compliant with EHB requirements, including the provision of MH/SUD services. The state aligns its ABP's outpatient benefits with those described in the state plan and applies the same prior authorization requirements. For outpatient MH/SUD services, prior authorization is required for each individual treatment session. In contrast, for outpatient medical/surgical services, a series of treatments is provided under a single authorization.

Example 9. Conclusion. In this example, the state's ABP design does not comply with the NQTL provisions of this rule. Although the same NQTL – prior authorization to determine

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medical appropriateness – is applied to both MH/SUD benefits and medical/surgical benefits for outpatient services, it is not applied in a comparable way.

Example 10. Facts. A state’s ABP requires preauthorization for all outpatient substance use disorder services. The state ABP does not require preauthorization for any medical/surgical services.

Example 10. Conclusion. The state ABP does not comply with the NQTL requirements in this rule. If a state ABP requires preauthorization for each outpatient SUD service it cannot remain in compliance if there is no comparable limitation on medical/surgical services.

Example 11. Facts. In cases where an MCO is unable to provide necessary outpatient services to a particular enrollee, the MCO requires that the enrollee must get prior approval in order to see any outpatient out-of-network provider. The MCO approves the use of an out-of-network provider for medical/surgical outpatient services if there is not an in-network provider within 10 miles of the person’s residence. Approval of an out-of-network provider for outpatient MH/SUD services is only authorized if there is not an in-network provider within 30 miles of a person’s residence.

Example 11. Conclusion. In this example, the MCO violates the NQTL provisions of this rule. The MCO is imposing a restriction that limits access to out-of-network providers. Although the same nonquantitative treatment limitation is applied to both the MH/SUD benefits and to medical/surgical benefits for outpatient services, it is not applied in a comparable way.

Example 12. Facts. A state contracts with MCO A to provide coverage for inpatient and outpatient mental health services to its Medicaid enrollees. MCO A requires prior authorization in person from MCO A’s staff for all inpatient admissions for any mental health condition. The state provides medical/surgical benefits to its Medicaid enrollees through a separate MCO (“MCO B”). MCO B does not require prior authorization in person but instead provides that

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authorization for an inpatient admission may be obtained from MCO B over the phone. The in-person prior authorization process for MCO A imposes a higher administrative burden on providers than the telephonic prior authorization, and in many cases also involves a longer waiting period for approval.

Example 12. Conclusion. In this example, MCO A violates the NQTL provisions of this rule. The in-person prior authorization requirement in MCO A applies to all inpatient mental health benefits whereas prior authorization may be obtained more easily and quickly over the phone for inpatient medical/surgical benefits in MCO B. MCO A is applying a stricter NQTL in practice to mental health and substance use disorder benefits than is applied to medical/surgical benefits.

Example 13. Facts. An MCO includes buprenorphine, a medication for treating opioid dependence, on its formulary. However, coverage is limited to one year total over a beneficiary's lifetime. The MCO does not apply this type of limit (a lifetime limit) to any other prescription drugs.

Example 13. Conclusion. In this example, the MCO violates the parity requirements for financial requirements and treatment limitations in this rule. The lifetime limit on coverage of this medication does not apply to substantially all medical/surgical benefits in the prescription drug classification.

Comment: A few commenters proposed additional, very specific criteria for determinations of whether a NQTL is applied to a given service. For example, one commenter suggested that the final rule stipulate that criteria including the following would justify the application of an NQTL to a MH/SUD service in a classification where similar NQTLs are not applied to medical/surgical services:

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- Treatments involving multiple services per session, with an increasing likelihood of medically unnecessary services with the higher number of services per session;
- Services with highly variable rates of progress for individual patients; and
- Services with highly variable treatment approaches among providers.

Response: We believe that the standards proposed and finalized in this rule and illustrated in the examples above in this section strike an appropriate balance between the need for clarity and the need to provide flexibility to regulated entities to determine the most effective way to structure the covered benefits: a NQTL may not be imposed for MH/SUD benefits in any classification unless, under the policies and procedures of the MCO, PIHP, or PAHP, or under the terms of the ABP or CHIP state plan, as written and in operation, any factors used in applying the NQTL to MH/SUD benefits in a classification are comparable to and applied no more stringently than factors used in applying the limitation for medical surgical/benefits in the classification. For these purposes, factors mean the processes, strategies, evidentiary standards, or other considerations used in determining limitations on coverage of services. Therefore, we are not providing additional criteria for determination of whether an NQTL is applied to a given service. If questions arise about the appropriateness of criteria that are being used to apply NQTLs to MH/SUD benefits, we will consider whether additional subregulatory guidance or further rulemaking is needed.

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Comment: Many commenters requested additional details to clarify what constitutes an NQTL and additional examples of typical parity violations. Most commenters also requested supplementary materials to provide further guidance, including information regarding typical violations as they are identified, along with regular and ongoing technical assistance to states and plans to help them implement the requirements of parity regarding NQTLs and to minimize the administrative burden related to this analysis.

Response: We clarify that all NQTLs imposed on MH/SUD benefits by regulated entities are to be applied in accordance with the requirements of this rule. We believe that the illustrative list of NQTLs provided in this final rule (§§438.910(d)(2), 440.395(b)(4)(ii), and 457.496(d)(4)(ii)) is sufficient to provide an understanding of the NQTLs that are commonly used in current health care practices. Given our attempts to align these provisions with the requirements of the MHPAEA final rules, we encourage interested parties to review guidance issued by Department of Labor (DOL), Department of Health and Human Services (HHS) and Department of the Treasury (Treasury) about application of the parity standards to group health plans and health insurance issuers. In addition, we will provide technical assistance to states regarding the implementation of these provisions and questions or issues that may arise. We will develop educational materials about the requirements of parity for Medicaid managed care, ABPs and CHIP programs, and about effective quality control strategies to ensure that managed care contracts include provisions that reflect best practices and promote quality of care in the context of parity. We will also identify and promote best practices and quality control strategies for states to help managed care organizations ensure that their benefits and service delivery strategies adhere to the requirements of parity.

Comment: Many commenters requested additional clarity on the application of parity requirements to provider networks, including additional examples. A few commenters noted that

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the proposed regulatory language regarding access to out-of-network providers differed slightly from the language of the general rule for NQTLs. Proposed §438.910(d)(3) provided that any MCO, PIHP or PAHP providing access to out-of-network providers for medical/surgical benefits within a classification, must use the same processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for MH/SUD benefits. In contrast, for other NQTLs the proposed rule required only that the factors used in applying the NQTL to MH/SUD benefits be comparable to and applied no more stringently than factors used in applying the limitation to medical/surgical benefits in the classification.

Response: We have revised this requirement in the final regulatory language. This final rule has been revised to require that the factors used to apply the limitation to MH/SUD benefits be “comparable to” and applied no more stringently than the factors used in applying the limitation to medical/surgical benefits in the classification. This language is in alignment with the general NQTL standard. We believe that it will reduce administrative burden on regulated entities and simplify enforcement to apply the same standard to all NQTLs. This final rule clarifies that the types of factors used to apply the NQTL will depend on the nature of both the NQTL and the benefit, and that in some cases it may be appropriate to use the same factors to apply the NQTL for both medical/surgical and MH/SUD benefits, whereas in other cases there may not be a single factor or set of factors that can practically be applied to both medical/surgical and MH/SUD benefits, and instead factors that are comparable may need to be used.

Comment: Many commenters requested that the rule address access to in-network providers. Several commenters also requested clarification regarding the interplay between proposed §438.910(d)(3) of the parity rule and §438.206(b)(4) of the existing managed care rule. The parity proposed rule stated that a plan complying with the network adequacy requirements of

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§438.206(b)(4) will be deemed in compliance with §438.910(d)(3), but commenters noted that §438.206(b)(4) does not stipulate the same requirements regarding parity in determining access to MH/SUD and medical/surgical providers. For this reason, commenters stated that finding provider networks to be in compliance with parity based only on adherence to §438.206(b)(4) would thwart the intent of the MHPAEA statute. Commenters also stated that it is unclear what the purpose of §438.910(d)(3) is if it requires nothing more than compliance with existing law.

Response: We agree and in this final rule, we removed the provision to deem compliance with §§438.910(d)(3) and 457.496(d)(5) of this rule (regarding parity requirements for access to out-of-network providers) where an MCO, PIHP, PAHP, or CHIP state plan is found to be in compliance with the provider network standard found in §438.206(b)(4). We clarify that compliance with §438.910(d)(3) and/or §457.496(d)(5) does not affect the requirement to comply with §438.206(b)(4). We may provide additional guidance or technical assistance to states regarding the requirements of §§438.206(b)(4) and 438.910(d)(3) and 457.496(d)(5) if questions persist. In response to the comments requesting that the rule address access to in-network providers, we also note that §§438.910(d)(2)(iii) and 457.496(d)(4)(ii)(C) include the example of an NQTL pertaining to network design for MCOs, PIHPs and PAHPs with multiple network tiers because although network tiers may not be used to impose financial requirements or quantitative treatment limitations in Medicaid and CHIP, we recognize that MCOs, PIHPs and PAHPs may still use them in developing NQTLs. For example, the MCO, PIHP, or PAHP may use network tiers when recommending providers to enrollees, or how they structure their provider directories. MCOs, PIHPs and PAHPs with multiple network tiers should be constructing them and providing beneficiary access to them in a way that is consistent with the parity standard for NQTLs.

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Comment: Many commenters expressed concerns about the ability of regulated entities to manage utilization of MH/SUD services under the proposed requirements. For example, one commenter requested that MCOs be provided the flexibility to require prior authorization of inpatient benefits for psychiatric admissions directly from emergency departments to ensure that enrollees have access to alternative crisis stabilization options, even where a parallel review is not needed for medical/surgical admissions.

Response: We disagree and we are finalizing this provision as discussed. The factors used to determine whether and when the use of prior authorization is appropriate must be comparable and applied no more stringently for MH/SUD benefits than they are for medical/surgical conditions.

Comment: Some commenters raised concerns about situations where medical/surgical services are provided through FFS and MH/SUD services are provided by an MCO, PIHP, or PAHP. The commenters expressed concern that because FFS delivery systems typically use extremely limited NQTL management of benefits, the MCO, PIHP, or PAHP will not be able to use any strategies to manage the utilization of MH/SUD services.

Response: Under this final rule, states have the flexibility to offer benefits through a variety of service delivery systems, and to employ financial requirements, quantitative treatment limits, and NQTLs as appropriate in alignment with the requirements of this rule. As stated earlier, we do not apply mental health parity requirements to state plan services provided to beneficiaries covered only through a FFS or PCCM delivery system, even if care for other beneficiaries is delivered through a managed care delivery system. However, as indicated in our 2013 SHO letter, we strongly encourage states to consider changes to the state plan benefit package to comport with the mental health parity requirements of section 2726 of the PHS Act.

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Benefits provided to an individual enrolled in an ABP or CHIP program are subject to parity regardless of how they receive their services, as explained in sections G and I.

We understand there could be instances where an MCO enrollee receives the majority of his or her services through a FFS delivery system. In those cases, the MCO will still need to deliver any MH/SUD services in compliance with these regulations; even if that means that the ability to use NQTLs is limited. However, states that contract with MCOs typically use them to deliver a comprehensive set of medical/surgical benefits.

Comment: Some commenters noted that in some delivery systems, the use of multiple delivery options (MCO, PIHP, and PAHP) results in segmentation of management of the benefit amongst different delivery system mechanisms. For example, a state may provide outpatient mental health benefits through the MCOs for the first 20 visits per year, but provide all additional visits through the FFS system.

Response: In this situation, because coverage for the service remains available to the beneficiary, we do not believe that this arrangement constitutes a quantitative treatment limit. Any requirements for prior authorization, concurrent review, or other NQTLs that are applied when the beneficiary begins receiving outpatient mental health services under FFS would be subject to the general parity analysis given this beneficiary is an enrollee of an MCO.

Comment: Some commenters requested clarification regarding the use of NQTLs for MH/SUD services where Diagnosis-Related Group (DRG) based reimbursement is used for medical/surgical services. Commenters stated that DRG-based reimbursement typically functions as an alternative to the use of NQTLs, and stated that it is not commonly used for MH/SUD benefits due to factors including higher variability in outcomes, lower predictability of length of stay, and related considerations regarding payment for MH/SUD services.

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Commenters questioned whether NQTLs may be used to manage utilization of MH/SUD services when DRG-based reimbursement is being used for medical/surgical services.

Response: The application of NQTLs to MH/SUD services is subject to the requirements of parity under this final rule. Thus, the use of concurrent review (a type of NQTL) for MH/SUD services in a classification would have to be based on processes, strategies, evidentiary standards or other factors that are comparable to and applied no more stringently than those used by the plan to determine when to use concurrent review for a medical service in the same classification. Some acceptable factors may include variability in outcomes and lower predictability in length of stay. In this scenario, the regulated entity would need to apply comparable criteria to medical/surgical services in a classification to determine whether to apply concurrent review to a MH/SUD service in that classification.

Comment: Many commenters recommended that no restrictions be allowed for MH/SUD medications that do not exist for medications used for medical/surgical treatment, including tiered drug formularies and other mechanisms used to limit access. Other commenters simply requested clarification regarding the application of the NQTL standard to prescription drugs, including formulary tiering standards that include off-label use. Commenters noted that Medicaid programs often impose limits on medications for MH/SUD, including limits on dosage, exclusion of certain medications used to treat SUD, lifetime limits on medications used to treat SUD, and complex initial prior authorization requirements.

Response: We note that all of these restrictions constitute quantitative or nonquantitative treatment limits that are subject to the parity analysis. However, we are not prohibiting the use of all quantitative or nonquantitative treatment limits for MH/SUD medications, as we believe these may be important tools for ensuring the appropriate management and delivery of effective MH/SUD treatments and services.

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Comment: Many commenters requested that Medicare Part D standards be integrated into this final rule to ensure non-discriminatory access to medications used for the treatment of mental illness and substance use disorders.

Response: While we agree that beneficiaries should have access to appropriate medications used for their treatment of medical/surgical and MH/SUD conditions, MHPAEA does not mandate the coverage of specific treatments, services, or drugs, and instead governs the limitations imposed on benefits that are offered. We believe that existing protections in Medicaid and CHIP programs are sufficient to ensure non-discriminatory access to medications used for the treatment of MH/SUD conditions. We also note that prescription drug coverage standards under Medicare Part D arise from different statutory provisions, funding mechanisms, and program requirements, than Medicaid and CHIP programs, and therefore are beyond the scope of this final regulation.

Comment: Many commenters requested the inclusion of additional examples to demonstrate the application of NQTL requirements to provider reimbursement, noting that reimbursement rates affect the sufficiency of network adequacy, which can limit access to care. One commenter noted that Medicaid and CHIP inpatient general acute services are typically reimbursed using methods tied to diagnosis and severity rather than category of service, but that this reimbursement methodology is not typically used for MH/SUD services.

Response: Similar to the guidance provided in the MHPAEA final rule, we clarify that regulated entities may consider a wide array of factors in determining provider reimbursement methodologies and rates for both medical/surgical services and MH/SUD services, such as service type; geographic market; demand for services; supply of providers; provider practice size; Medicare reimbursement rates; and training, experience and licensure of providers. The NQTL provisions require that these or other factors be applied comparably to and no more

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stringently than those applied for medical/surgical services, noting that disparate results alone do not mean that the NQTLs in use fail to comply with these requirements.

After consideration of the comments received and further analysis of the reasons described in the proposed rule, we are revising the provisions proposed in §438.910(d)(3) and §457.496(d)(5) by finalizing them without the language to deem compliance with §438.910(d)(3) and §457.496(d)(5) of this final rule (regarding parity requirements for access to out-of-network providers) where an MCO, PIHP, or PAHP is found to be in compliance with the provider network standard found in §438.206(b)(4). We are also revising the provisions in §§438.910(d)(3) and 457.496(d)(5) to require that the factors used to apply the limitation to MH/SUD benefits be “comparable to” and applied no more stringently than the factors used in applying the limitation to medical/surgical benefits in the classification, rather than requiring that the “same” factors be applied to both sets of benefits. We are also finalizing a technical change in the punctuation and the placement of the word “and” in §457.496(d)(4)(ii)(G) and (H) to increase clarity in the final rule regulation text. With the exception of these revisions, as indicated in the response to comments, we are finalizing the provisions regarding NQTLs at §§438.910(d), 440.395(b)(4), and 457.496(d)(4) and (5) as proposed.

G. Parity for Mental Health and Substance Use Disorder Benefits in CHIP Programs Covering EPSDT (§457.496(b))

Consistent with section 2103(c)(6)(B) of the Act, we proposed at §457.496(b) to deem a separate CHIP compliant with mental health parity requirements if the state provides EPSDT in accordance with section 1905(r) of the Act. Proposed §457.496(a) included a definition of EPSDT by cross reference to section 1905(r) of the Act, which specifies the scope of services and supports that must be provided as well as the medical necessity standard applicable to individuals entitled to EPSDT. However, to be deemed compliant with the mental health parity

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requirements, section 2103(c)(6)(B) of the Act also requires that a separate CHIP provide EPSDT benefits in accordance with section 1902(a)(43) of the Act. This requirement was not adequately addressed in the proposed regulation. Therefore, as discussed below in this final rule, we are modifying §457.496(b) in the final rule to reflect that compliance with the requirements at section 1902(a)(43) of the Act is also necessary in order for a separate CHIP to be deemed compliant with parity provisions. We are also revising several proposed definitions set forth in §457.496(a) as discussed later in this section of the final rule.

We received the following comments on these proposed provisions.

Comment: The majority of commenters were generally supportive of the application of parity requirements related to mental health/ substance use disorder (MH/SUD) benefits to CHIP. However, many commenters expressed concern about deeming CHIP programs compliant based solely on coverage of EPSDT benefits. In particular, they emphasized the need for greater oversight of states' compliance with providing the full range of services included within the scope of EPSDT, citing lawsuits in which children enrolled in Medicaid allegedly have been denied access to MH/SUD treatment even though the state is required to cover MH/SUD services as part of the EPSDT benefit. Some commenters noted that a few separate CHIP plans indicate that they provide EPSDT benefits, but in fact, apply limitations or exclude benefits that must be covered under the EPSDT benefit in Medicaid. Commenters recommended that CMS scrutinize the coverage under CHIP to ensure that programs deemed compliant are in fact providing EPSDT benefits as defined under the Medicaid statute. Commenters were particularly concerned about the application of treatment limitations, including NQTLs, to MH/SUD benefits compared to medical/surgical benefits for children enrolled in separate CHIPs that cover EPSDT under the CHIP state plan. Some commenters suggested not providing for deemed compliance at all.

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A few commenters were supportive of deeming separate CHIPs as compliant with MHPAEA strictly based on the state plan indicating that EPSDT benefits are covered for the population, and were opposed to considering other criteria, such as an examination of treatment limits, cost sharing, and NQTLs.

Response: We agree that EPSDT is a critical benefit that ensures children, adolescents, and young adults under age 21 have access to a comprehensive benefit package and other medically necessary services tailored to meet their needs. While we understand some commenters are concerned that implementation of EPSDT in Medicaid may not fulfill the requirements of the statute across all states, implementation of EPSDT in state Medicaid programs is a compliance issue that is beyond the scope of this regulation.

However, we appreciate commenters' concerns that it is not sufficient that the state plan only indicate coverage of EPSDT under a separate CHIP in order to be deemed compliant with mental health parity requirements. We also agree with commenters that separate CHIPs that exclude benefits or place limits on benefits that are not consistent with the scope of EPSDT under the Medicaid statute should not be considered eligible for deemed compliance with mental health parity requirements. Section 2103(c)(6)(B) of the Act provides that CHIPs covering EPSDT benefits are deemed compliant with parity requirements under MHPAEA. Specifically, section 2103(c)(6)(B) provides that a separate CHIP which provides EPSDT benefits and services consistent with sections 1905(r) and 1902(a)(43) of the Act are deemed compliant with the mental health parity requirements, and we have retained that statutorily-prescribed policy in the final regulation.

Section 1905(r) of the Act requires states to provide screening and diagnostic services as well as any medically necessary health care services, or treatments covered under section 1905(a) of the Act needed to correct or ameliorate defects and mental and physical illnesses or

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conditions, regardless of whether the service is covered under the Medicaid state plan. This allows for a broad array of services to be available under EPSDT such as rehabilitative and therapy services, counseling, personal care services, immunizations, periodic comprehensive well-child checkups and screenings for vision, hearing, and dental care, even if not covered for adults under the Medicaid state plan. Section 1905(r) of the Act also requires states to provide screening services at intervals that align with periodicity schedules that meet reasonable standards of medical or dental practice. Section 1902(a)(43) of the Act requires states to provide and arrange for these medically necessary screenings, diagnostic services, and treatments, and to inform individuals under 21 in Medicaid about the availability of the full range of EPSDT services available to them. Separate CHIP programs that comply with these statutory requirements will be considered to provide “full” EPSDT in their separate CHIPs and will be deemed compliant with the parity requirements. Separate CHIPs that do not comply with all of the statutory requirements in sections 1905(r) and 1902(a)(43) of the Act will not be deemed compliant; compliance for these programs will be based on satisfaction of the standards set forth in §457.496.

In response to commenters’ concerns that separate CHIPs will be deemed compliant with MHPAEA without providing the full scope of EPSDT benefits and supports, we are modifying §457.496(b) of the final regulation to provide, with new language at paragraph (b)(1), that to be deemed compliant with the mental health parity requirements under §457.496, a state must elect in its state plan to cover all EPSDT services required under section 1905(r) of the Act, as well as meet the informing and administrative requirements under section 1902(a)(43) of the Act and the approved State Medicaid plan. We are also adding new language at paragraph (b)(2) to require that the child health plan include a description of how the state will comply with the applicable Medicaid statute and the requirements of paragraph (b)(1)(i). The exclusion of services for

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particular conditions or diagnoses is also not permitted under section 1905(r) of the Act for individuals under 21 entitled to EPSDT services. Therefore, we have added a provision at §457.496(b)(1)(ii) to preclude separate CHIPs from excluding any particular condition, disorder, or diagnosis under EPSDT benefits. We are also revising the meaning of EPSDT at §457.496(a) to include references to both sections 1905(r) and 1902(a)(43) of the Act. We are not finalizing the proposed text that referred to “expansion of Medicaid programs” which we believe was confusing since the regulation applies only to separate CHIP programs.

In evaluating whether a state is fully compliant with the statutory requirements governing EPSDT benefits with respect to children enrolled in its separate CHIP, we will consider whether there are any outstanding compliance issues associated with the state’s provision of EPSDT in its Medicaid program. While we recognize that in some states, the Medicaid and CHIP programs may not be identical and/or administered by different agencies, what is critical to be deemed compliant with the mental health parity requirements is that the provision of EPSDT in CHIP is compliant with the requirements in sections 1902(a)(43) and 1905(r) of the Act. For example, if a separate CHIP covers all benefits identified in section 1905(a) of the Act in accordance with the requirements set forth in section 1905(r)(5) of the Act, we would deem compliance with parity requirements in this final rule only if the separate CHIP also had procedures to inform individuals of the availability of those services, provide or arrange for screening services, and assure necessary transportation as part of the administration of those benefits as required by section 1902(a)(43) of the Act.

States that elect to apply any type of NQTLs under their separate program must ensure that such limits are consistent with EPSDT requirements at section 1905(r)(5) of the Act. We will closely review states’ NQTLs to ensure that they meet deemed compliance standards under §457.496(b). For example, states will have the discretion to exclude some experimental services,

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and this type of NQTL would be unlikely to present a barrier to deemed compliance. Conversely, annual and lifetime limits are not consistent with Medicaid and/or EPSDT, and this practice would preclude a state from deemed compliance.

Finally, we have added paragraph (b)(3) to §457.496 to be clear that if a state has elected in its state child health plan to cover EPSDT benefits only for certain children eligible under the state child health plan, the state is deemed compliant with this section only with respect to such children.

Comment: Some commenters recommended that the states should submit documentation beyond state plan assurances to show how they plan to meet parity requirements. Furthermore, commenters were concerned that separate CHIPs deemed compliant with parity regulations would apply NQTLs to MH/SUD benefits in a manner that is not comparable to or is more restrictive than the NQTLs applied to medical/surgical benefits.

Response: We will develop a state plan amendment (SPA) template for states to use in indicating how they will comply with the requirements of §457.496. For states that report providing EPSDT, we anticipate asking them to attest that the full EPSDT benefits being offered to children in the separate CHIP, as described in section 1905(r) of the Act, are being provided in a manner that is compliant with section 1902(a)(43) of the Act.

States will also be required to affirm in their state plan that the processes, strategies, evidentiary standards, or other factors used in applying NQTLs to MH/SUD benefits are comparable to and applied no more stringently than those used in applying the limitation to medical/surgical benefits. As a part of the review process, we will work closely with states to ensure compliance with the parity requirements and assist states in their efforts to address any inconsistencies discovered during the review process.

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Comment: Commenters expressed concern about how states not providing EPSDT in CHIP would document compliance with MHPAEA. One commenter asked for clarification about the assurances states will provide when submitting their CHIP state plan amendments to CMS.

Response: For CHIP programs that do not provide full EPSDT benefits (and therefore do not meet the deeming requirements), a full benefit and cost sharing analysis of the CHIP state plan must be conducted by the state to determine compliance with the parity standards in this final rule. The state's parity analysis must also include an examination of the processes, strategies, evidentiary standards, and other factors used in the application of NQTLs to MH/SUD benefits. The state must ensure these factors are comparable to and applied no more stringently than those used in applying NQTLs to medical/surgical benefits in the same classification. We will develop a state plan template to facilitate this analysis.

Comment: Another commenter expressed concerns about lack of current tracking of certain mental health benefits that are required under EPSDT because they are not reported on the CMS-416 form.

Response: The CMS-416 mandatory reporting form does not include a measure specific to any mental health screenings, diagnostic methods, or treatments. The CMS-416 is primarily focused on defining the number of children eligible for EPSDT, the overall number of screenings these children receive, and oral health and dental care measurements. However, section 401 of the CHIPRA required that the HHS Secretary develop a standardized set of measures for voluntary state use relating to a variety of topics within children's health. The initial Child Core Set was published in February 2011 and has been expanded to include measures specific to behavioral health. We will continue our efforts to collaborate with states to improve the quality of the behavioral health measures data. Additional information on the Child Core Measurement

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Set is available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/CHIPRA-Initial-Core-Set-of-Childrens-Health-Care-Quality-Measures.html>.

Comment: Many commenters recommended clarifying what medically necessary services separate CHIP programs are required to provide through EPSDT, such as home services and intensive care coordination.

Response: EPSDT is a required Medicaid benefit for categorically needy individuals under age 21 that entitles these individuals to medically necessary services, as described in section 1905(a) of the Act, to treat physical or mental illnesses or conditions, whether or not these services are otherwise covered under the Medicaid state plan. Under section 1905(r)(5) of the Act, the EPSDT benefit includes services necessary to correct or ameliorate defects and physical or mental illnesses and conditions discovered by screening services. To be deemed compliant with the parity requirements under §457.496(b) of the final regulations, the coverage of EPSDT under a separate CHIP requires the same scope of coverage that a child covered by Medicaid would receive-- that is, a CHIP enrollee would have to be entitled to all benefits and services described in section 1905(a) of the Act if medically necessary and consistent with section 1905(r) of the Act. We believe that including a list of specific services that are required to be provided under EPSDT is outside of the scope of this regulation. Additional information on the scope of benefits required under the EPSDT benefit can be found in “EPSDT - A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents,” available at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/downloads/epsdt_coverage_guide.pdf.

Comment: One commenter noted that applied behavior analysis (ABA) is another service that is considered a medically necessary service that must be provided under EPSDT.

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Response: Whether or not a specific service is medically necessary for a particular child is beyond the scope of this final rule. However, we direct the commenter to the CMCS Informational Bulletin “Clarification of Medicaid Coverage of Services to Children with Autism” at <https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-07-07-14.pdf>, and the frequently asked question issuance entitled “Services to Address Autism”, which discusses the provision of ABA therapy under EPSDT, available at <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/FAQ-09-24-2014.pdf>.

Comment: Many commenters expressed concern that the exclusion of coverage for services related to specific diagnoses is not considered a treatment limitation under this rule. Commenters believed that excluding benefits for certain diagnoses or conditions would directly conflict with current Medicaid regulations that prohibit discrimination based on diagnosis and could lead to states not fulfilling their obligations. Many commenters believed that states would view the proposed regulation as superseding current regulations. To avoid this confusion, many commenters suggested adding clarifying language that the proposed regulation does not trump the state’s obligation to comply with current Medicaid regulations regarding discrimination based on diagnosis or other legislation such as the Americans with Disabilities Act (ADA). Other commenters recommended not including the exclusion in the final regulations.

Response: In this final rule we maintain the definition of “treatment limitation” set forth at §457.496(a) in the proposed rule under which a permanent exclusion of all benefits for a particular condition or disorder is not a treatment limitation. This definition aligns with the definition of “treatment limitation” provided in the MHPAEA final regulations (the final rules applicable outside of Medicaid and CHIP, as defined in section II of this final rule). As previously discussed, we agree that states providing EPSDT benefits in their separate CHIP must be compliant with the all requirements associated with EPSDT in the Medicaid statute.

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Exclusion of treatment for any conditions is not permitted under section 1905(r) of the Act for individuals under age 21 who are enrolled in Medicaid, so if a separate CHIP excludes coverage for particular conditions, disorders, or diagnoses, that separate CHIP will not be considered as providing EPSDT benefits consistent with section 1905(r)(5) of the Act. Therefore, states which exclude treatment for particular conditions, disorders, or diagnoses cannot be deemed compliant with the mental health parity requirements under §457.496(b) of the final regulations. In response to comments, we have added language in §457.496(b)(1)(ii) to expressly provide that a separate CHIP cannot be deemed compliant with mental health parity requirements under the final regulation if it excludes benefits for a particular condition, disorder, or diagnosis.

In considering the comments received, we are finalizing the provisions proposed in §457.496(a) with modifications to revise the definition of EPSDT benefits to specify that, for the purposes of §457.496, EPSDT benefits means benefits defined in section 1905(r) of the Act that are provided in accordance with section 1902(a)(43) of the Act to mirror the statutory requirement in section 2103(c)(6)(B) of the Act regarding deemed compliance. Additional changes to proposed definitions in paragraph (a) include the modification of “CHIP State Plan” to “State Plan” in order to use terminology consistent with existing CHIP regulations.

Furthermore, §457.496(b) is being finalized with substantive changes and a technical change to clarify the standards which must be met to be deemed compliant with §457.496, including the provision of all EPSDT benefits as defined in section 1905(r) of the Act, and compliance with requirements for providing EPSDT benefits in accordance with section 1902(a)(43) of the Act. Additional language is also being incorporated to clarify that the state plan must include a description of how the state will comply with the EPSDT deeming requirements in §457.496(b).

H. Availability of Information (§438.915, §440.395(d), §457.496(e))

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Under the MHPAEA final regulations at §146.136 (d)(1), the criteria for medical necessity determinations made under a group health plan or health insurance coverage for MH/SUD benefits must be made available by the plan administrator or the health insurance issuer offering such coverage in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request, in accordance with section 2726(a)(4) of the PHS Act. Under the same authority, the MHPAEA final regulations also require at §146.136(d)(2) that the reason for any denial under a group health plan or health insurance coverage of reimbursement or payment for services for MH/SUD benefits in the case of any participant or beneficiary be made available, upon request or as otherwise required, by the plan administrator or the health insurance issuer to the participant or beneficiary. The proposed rule also addressed these issues.

We proposed to apply these disclosure requirements imposed on the health insurance issuer under MHPAEA and the MHPAEA final regulations regarding availability of information in a similar manner to MCOs and to PIHPs and PAHPs that provide coverage to MCO enrollees. As proposed and finalized in this rule in §438.915(a), MCOs, PIHPs, and PAHPs subject to parity requirements must make their medical necessity criteria for MH/SUD benefits available to any enrollee, potential enrollee or contracting provider upon request. We proposed that MCOs, PIHPs, and PAHPs found to be in compliance with §438.236(c), which requires dissemination by MCOs, PIHPs and PAHPs of practice guidelines to all affected providers, and, upon request to enrollees and potential enrollees, will be deemed to meet this requirement. In addition, we proposed in §438.915(b) to require MCOs, PIHPs, or PAHPs to make available the reason for any denial of reimbursement or payment for services for MH/SUD benefits to the enrollee. As noted in the proposed rule, §438.210(c) already requires each contract with an MCO, PIHP, or PAHP to provide for the MCO, PIHP, or PAHP to notify the requesting provider and give the

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enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested.

Although the statute that applies MHPAEA to ABPs does not include specific provisions regarding the availability of plan information, in the proposed rule we proposed to use our authority under section 1902(a)(4) of the Act to extend this provision to all ABPs, as well as those ABPs with services delivered through MCOs, PIHPs and all PAHP. This final rule retains this provision. At §440.395(c)(1), we proposed that all states delivering ABP services through a non-MCO must make available to beneficiaries and contracting providers on request the criteria for medical necessity determinations for MH/SUD benefits. Similarly, §440.395(c)(2) in the proposed rule required the state to make available to the enrollee the reason for any denial of reimbursement or payment for services for MH/SUD benefits. For the same reasons, using our authority under section 2101(a) of the Act, we proposed at §457.496(e) to require disclosure, upon request, to any current or potential CHIP enrollee or contracting provider of the criteria for medical necessity determinations and to require that the reason for any denial of reimbursement or payment for MH/SUD benefits be made available to the enrollee. As proposed, the CHIP rule would also apply to managed care plans, so we included a provision in that proposal for deeming compliance with the parity disclosure requirement if the managed care entity complied with §438.236(c) disclosure requirements. We also proposed for CHIP plans that other laws requiring disclosure would still apply.

The MHPAEA final regulations at §146.136(d)(2) state that non-federal governmental group health plans (or health insurance coverage offered in connection with such plans) that provide the reason for claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503-1 for group health plans will be found in compliance with the MHPAEA

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disclosure requirements for denials.⁸ The standards at 29 CFR 2560.503-1 do not themselves apply to Medicaid; we did not propose in this rule to make them applicable as a condition for deemed compliance because similar requirements are already applicable under existing law. MCOs, PIHPs, PAHPs and states are required to give a “reason” for any adverse benefit determinations under requirements for notices in, respectively, §438.404 and §431.210. The information provided in this disclosure of the reason for the adverse benefit determination must be made in compliance with these and all other provisions of applicable federal or state law.

For similar reasons, the proposed rule did not make claim denial requirements of 29 CFR 2560.503-1 a condition of deemed compliance for CHIP programs. CHIP enrollees have an opportunity for an external review of denials, reduction or suspension of health services under §457.1130.

We requested comments on any additional provisions concerning the availability of plan information or notice of adverse determinations that may be necessary to facilitate compliance with MHPAEA for MCOs, PIHPs, PAHPs, ABPs, and CHIP.

Comment: Some commenters expressed concern that the requirements for MCOs, PIHPs, and PAHPs that are specific to parity compliance were less stringent than the disclosure requirements that apply to commercial plans under the final MHPAEA rule. The commenters recommended that the final rule be revised to set more specific standards for the release of medical necessity determinations.

Response: We disagree and believe the proposed rule set forth the same standards regarding availability of medical necessity information for MCOs and to PIHPs and PAHPs that provide coverage to MCO enrollees that are imposed on the health insurance issuer through

⁸ The requirements of 29 CFR 2560.503-1 are applicable to ERISA plans, as well as all non-grandfathered group health plans and health insurance issuers in the group and individual markets, through the claims and appeals regulations adopted under the Affordable Care Act. See 78 FR 68247 for a full discussion .

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section 2726 of the PHS Act and the MHPAEA final regulations. We proposed and are finalizing the regulation at §438.915(a) to provide that MCOs, PIHPs and PAHPs subject to MHPAEA requirements must make their medical necessity criteria for MH/SUD benefits available to any enrollee, potential enrollee or contracting provider upon request.

Comment: Some commenters were concerned that the proposed rule did not have the same claims denial requirements as required for group health plans. The commenters recommended that CMS require MCOs, PIHPs, and PAHPs to provide the reason for a claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503-1. In addition, some commenters suggested that CMS establish a firm timeframe for the release of such information and for the release of claims denials. Several commenters recommended that CMS establish penalties for Medicaid MCOs, CHIP plans and ABPs that fail to make plan information available in a timely and easily accessible manner.

Response: As we stated in the proposed rule, the provisions under 29 CFR 2560.503-1 do not themselves apply to Medicaid and CHIP and we did not see a reason to propose to extend those provisions to Medicaid and CHIP. There is a disclosure requirement applicable in Medicaid and CHIP. MCOs, PIHPs, PAHPs and states are required to give a “reason” for any adverse benefit determinations under requirements for notices in, respectively, §438.404 and §431.210. CHIP enrollees have an opportunity for an external review of denials, reduction or suspension of health services under §457.1130. There are current rules that do require states to provide notice of adverse action within certain timeframes and (§432.211 and §432.213). In addition, there is specific information that must be included in a notice of action to a beneficiary including: the action, reason for the action, right to appeal and the right to continue benefits pending the result of the appeal (§438.404). Therefore, we do not believe it is necessary or appropriate to adopt additional general disclosure standards in this rule.

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Comment: Many commenters expressed concern that the proposed rule would not provide beneficiaries, providers and stakeholders with comparable information regarding medical necessity standards for medical/surgical service, and therefore, would not provide sufficient information to compare medical necessity requirements for MH/SUD against similar requirements for medical/surgical services. The commenters recommended the rule should specify that information about criteria used for making medical necessity determinations for comparable medical/surgical treatment should be provided to plan beneficiaries and providers upon request.

Response: The current managed care rules §438.236 do require Medicaid managed care plans to provide practice guidelines (including medical/surgical and MH/SUD) to enrollees and potential enrollees. Additionally, §431.210 and §438.404 require MCOs, PIHPs, PAHPs and states (for state fair hearings) to provide the reason for a denial. In addition, under §438.404 beneficiaries can be provided medical necessity criteria for medical/surgical benefits as well as MH/SUD benefits. In addition, §438.402 allows providers acting on behalf of beneficiaries to file a grievance to request and receive information.

In regards to CHIP, under §457.1130 and §457.1180, beneficiaries have the right to an external review related to health service matters and must receive a notice that includes the reasons why a determination was made. We believe these requirements allow beneficiaries to request and receive the necessary medical necessity information especially in terms of a denial to make a determination that access to the service is in compliance with these rules.

Comment: Some commenters expressed concern that transparency should not be predicated upon Medicaid and CHIP beneficiaries having the knowledge and wherewithal to request information from health plans after specific services have been denied. These commenters made several recommendations to improve this transparency. Some commenters

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recommended that plans be required to provide beneficiaries and, when appropriate, providers with written criteria for medical necessity determinations whenever requests for MH/SUD services are denied rather than requiring beneficiaries request this information.

Response: We agree that transparency is important and we would like to remind beneficiaries and providers that they can request that information at any time. However, providing written criteria for medical necessity determinations to all beneficiaries when services are denied may be overwhelming for all beneficiaries and may be administratively burdensome for states and MCOs, PIHPs and PAHPs. Therefore, we are not imposing a requirement in this final rule to provide beneficiaries and, when appropriate, providers with written criteria for medical necessity determinations whenever requests for MH/SD services are denied.

Comment: Commenters recommended that MCOs, PIHPs, and PAHPs should be required to publish their medical necessity criteria for MH/SUD treatment and medical/surgical treatment on their websites and in other formats easily accessible to consumers, families, and treatment providers including requirements for persons with limited English proficiency or disabilities. Some commenters made other recommendations to improve health plans' transparency, including a request that MCOs, PIHPs, and PAHPs should be required to periodically publish information about denial rates for inpatient and outpatient MH/SUD treatment and denial rates for inpatient and outpatient medical/surgical treatment which would allow states to identify possible issues with parity compliance and to take necessary actions to ensure that the provisions of this rule are enforced.

Response: We believe that existing requirements in §438.236 (governing the adoption, dissemination and application of practice guidelines by MCOs, PIHPs and PAHPs) as well as the requirements in §438.10 mandating that member materials be provided in alternative formats is sufficient for providing the necessary information to beneficiaries. We also believe that the

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language in §438.10 can be interpreted to include posting information on the website as that modality becomes more available to individuals enrolled in Medicaid. However, we would encourage states to post this information regarding practice guidelines on their website. We are providing technical assistance to states regarding the data and information that would be helpful to review to identify possible issues with plans' efforts to understand and comply with parity. Further, we believe that data regarding denial rates across classifications will be important information for states to analyze and determine if there are potential issues with complying with the provisions of this rule and taking corrective action when appropriate with their MCOs, PIHPs, or PAHPs.

Comment: Several commenters raised concerns that additional requirements regarding the availability of information could have unintended consequences. One example of such consequences included duplicating or complicating existing efforts to ensure transparency and adequate information to enrollees; another example suggested that additional requirements would make it more difficult for members to navigate the available information and could also divert plan resources away from Medicaid beneficiaries who were enrolled in managed care. Several commenters noted that current Medicaid regulations already provide sufficient protections for Medicaid and CHIP enrollees regarding medical necessity determinations indicating that CMS already requires Medicaid MCOs to notify the requesting provider and/or give the enrollee written notice of any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested. In addition, the commenters indicated that the Medicaid program already has disclosure requirements concerning the availability of plan information and notice of adverse determinations and those should be followed instead of increasing the administrative burden for states and plans by creating new requirements specific to parity. The commenters stated that creating additional or new requirements would increase

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the administrative and operational burden for both plans and states. One commenter recommended that if additional guidance was needed, subregulatory guidance, such as a State Medicaid Director Letter, could address some of the complexities around availability of information such as medical necessity and adverse determination notices. Another commenter recommended that CMS engage states, accreditation organizations, and Medicaid managed care plans to better understand activities already occurring before layering on additional monitoring requirements on states and plans.

Response: We believe that current Medicaid and CHIP regulations provide sufficient disclosure to current beneficiaries; the proposed regulation solidifies a provider's ability to obtain medical necessity information. The current provisions require MCOs, PIHPs or PAHPs to provide their medical necessity criteria for mental health and substance disorder benefits to beneficiaries and affected providers. We proposed and are finalizing §438.915(a) that will require the plan administrators to provide such medical necessity criteria to any contracting provider. We believe that an affected provider in §438.236(c) is consistent with this definition because given certain referral practices in place within an MCO, PIHP or PAHP; providers may need to understand practice guidelines for more than their area of expertise.

Comment: One commenter expressed concern regarding issues with sharing medical necessity criteria because the proposed provisions (and this final rule) require provision of medical necessity criteria or practice guidelines to enrollees and prospective enrollees as well as participating providers. Specifically, this commenter recommended that CMS specify that licensed and proprietary criteria should not be made available unless such criteria are relevant to specific treatments or services and are requested by current or prospective insured patients, or healthcare providers with appropriate notice of disclosure of confidential and proprietary information.

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Response: We agree with the commenter that this final rule requires information regarding the medical necessity criteria for specific treatments be made available upon request to current or prospective beneficiaries or health care provider; this final rule does not require that this information be more broadly disseminated to the general public.

Comment: Another commenter recommended that CMS require states to engage all stakeholders in an open and public process on the state's plans to comply with the parity requirements.

Response: While the regulation requires states to post information on their parity analysis on the state website, the proposed rule did not address stakeholder engagement regarding states' efforts to determine if MCOs or other delivery systems were parity compliant. Without prior notice and opportunity for comment, we do not believe it appropriate to finalize a requirement that states develop stakeholder engagement processes regarding their efforts to review compliance with the final regulation. However, we do encourage states to undertake these efforts and to include stakeholders as much as possible.

Comment: One commenter recommended that CMS require states to educate both beneficiaries and providers regarding any new benefit changes.

Response: We agree that beneficiary education is important which is shown in current managed care regulations under §438.10. Section 438.10(f) currently specifies that enrollees must be notified of their benefits available under the MCO, PIHP or PAHP contract, how to obtain a prior authorization, how the enrollee can obtain benefits including benefits that are available under the state plan but not covered under the contract. Enrollees must be notified at the time of enrollment and also at any time a change to the benefits or processes listed here is considered significant.

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Comment: Another commenter recommended CMS consider including, or clarifying, the ability of a Medicaid beneficiary to designate a personal representative with the legal authority to request information from the MCOs regarding medical necessity criteria and the basis of service denials.

Response: Currently parents or legal guardians of children participating in the Medicaid or CHIP program may request the medical necessity criteria or receive information on service denials. Individuals that have a power of attorney for an individual would also have authority to make these requests. In addition, §438.406(b)(4) provides that the enrollee and his or her representative must be included in the appeals process.

As indicated in the response to comments, we are finalizing the provisions regarding availability of information at §438.915, §440.395(d), §457.496(e) as proposed with a technical change in §457.496(e)(1) to use the term “deemed” in place of “determined.” There was an oversight of an inconsistency between the corresponding Medicaid regulations at §438.915 that has been corrected in this final rule.

I. Application to EHBs and other ABP Benefits (§440.395(c), §440.395(e)(1))

Section 1937(b)(6) of the Act, as added by section 2001(c) of the Affordable Care Act, and implemented through regulations at §440.345(c) directs that ABPs that provide both medical and surgical benefits and MH or SUD benefits must comply with certain parity requirements. Further, ABPs must provide the 10 EHBs, including MH/SUD services. As states determine their ABP service package, states must use all of the EHB services from the base-benchmark plan selected by the state to define EHBs, consistent with the applicable requirements in 45 CFR part 156.

Section 1937 of the Act offers flexibility for states to provide medical assistance by designing different benefit packages, including other services beyond the EHBs for different

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groups of eligible individuals, as long as each benefit package contains all of the EHBs and meets certain other requirements, including parity provisions under section 2726 of the PHS Act.

While we did not request comment specifically on this section, we did receive many comments on ABPs. For the reasons set forth below, we are finalizing the proposed provisions at paragraphs (c) and (e)(1), with modification, which we describe below.

Comment: Several commenters remarked on various topics regarding the intersections between MHPAEA requirements and ABPs. Several commenters requested that we clarify if parity requirements differ by type of ABP such as ABPs that offer only state plan benefits or ABPs that serve medically frail beneficiaries and have benefits that are more than the state plan benefits.

Response: Consistent with the proposed rule, the final regulation requires every approved ABP to meet parity requirements, regardless of the benefit package offered by the ABP. In final §440.395, we address ABPs that are provided other than through a managed care delivery system and in final §438.900 through §438.930, we address ABPs that are delivered through MCOs, PIHPs and PAHPs. As noted throughout this rule, the parity standards are virtually identical in these different regulations.

Comment: Additional commenters noted that section 1937(b)(6)(B) of the Act specifies that ABP coverage providing EPSDT should be deemed compliant with parity.

Response: We agree with the commenter. We are therefore finalizing §440.395(c) to implement the statutory deeming provision for ABPs.

Comment: Many commenters believed that CMS afforded states too much discretion regarding how parity analyses are conducted for EHB in ABPs and provided too little oversight of state processes used and how services are offered (that is, whether services are offered through managed care contracts or in fee for service (FFS) arrangements). Several commenters requested

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that CMS provide more structured requirements or a mandatory methodology for such analyses in ABPs; one commenter wanted CMS to conduct a comprehensive review of EHBs in all ABPs with special attention on intermediate behavioral healthcare services.

Response: We are not adding additional requirements or a mandatory methodology in this final rule with regard to our proposal that states oversee the parity analysis for EHBs in ABPs. This final rule provides that states have oversight responsibility for ensuring parity in ABPs, similar to their responsibility for ensuring parity in managed care contracts. However, we will provide technical assistance to states regarding the implementation of these provisions and questions or issues that may arise. This technical assistance may include the identification and promotion of best practices, tools, and/or other assistance for analyzing ABPs for compliance with the requirements of this rule.

Comment: One commenter noted that the proposed rule NQTL requirements for ABPs mirrors the requirements for group health insurance plans, offering states flexibility in designing NQTLs on a benefit by benefit basis.

Response: We appreciate the commenter's feedback and agree this was the intent of the proposed rule and is maintained in the final rule.

Comment: One commenter asked CMS to confirm that §440.396 Benchmark and Benchmark-Equivalent Coverage that was reviewed and approved by CMS has been determined to be in compliance with parity.

Response: We have reviewed all approved ABPs for parity compliance and states have attested to their compliance with MHPAEA in the ABP SPAs. New SPA applications that are submitted to create ABPs will be reviewed by CMS to determine if the plan complies with this final rule.

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Comment: Many commenters requested clarification and examples about how parity applied to long term services and supports in ABPs for EHB. The commenters believe that many of the EHBs in ABPs include long term services and that the Affordable Care Act does not allow such long term benefits offered for SUD/mental health to be more restrictive than long term medical/surgical benefits.

Response: We have included long term services and supports in the definition of medical/surgical benefits, mental health benefits and substance use disorder benefits as such terms are defined and used in this final rule. (See section III.A. of this final rule for a more detailed discussion). Therefore, this rule is clear that parity standards apply to these services.

As indicated in the response to comments, we are finalizing the substance of the applicability standard as proposed in §440.395(d)(1); we note that this provision is being designated as §440.395(e)(1) in this final rule because of the addition of regulation text to address EPSDT in the context of ABPs and the parity requirements. In addition, a comma was added to this text (which follows the word “PAHP”) for grammatical reasons. Further, we are finalizing regulation text, in §440.395(c), to deem compliance with the parity provisions when an ABP covers EPSDT.

J. ABP State Plan Requirements (§440.395(e)(3))

We proposed to require states using ABPs to provide sufficient information in the ABP state plan amendment to assure and document compliance with parity provisions. The requirement was included in the proposed rule at §440.395(d)(3) and is being re-designated as §440.395(e)(3) in the final rule.

Comment: Some commenters stated that there is no stipulation in the preamble or proposed regulations that define a required methodology and/or documentation of the analysis to determine if an ABP complied with parity where ABPs are provided on a FFS basis. The

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commenters maintained that the state has no responsibility to the public to disclose its documentation of compliance other than providing sufficient information to CMS.

Response: To clarify, where ABPs are provided on a FFS basis, this regulation would require states to provide sufficient information in the ABP state plan amendment request to assure and document compliance with parity requirements. We will review the plan amendment to assure compliance with parity requirements and EHB anti-discrimination provisions.

We are finalizing this provision as proposed, with a different designation, at §440.395(e)(3).

K. Application of Parity Requirements to the Medicaid State Plan

The provisions of section 2726 of the PHS Act that are incorporated through sections 1932 and 1937 of the Act do not apply directly to the benefit design for Medicaid fee-for-service and non-ABP state plan services. Under the proposed rule, the requirements would apply to the benefits offered by the MCO (or, as discussed above, if benefits are carved out, to all benefits provided to MCO enrollees regardless of service delivery system) but did not apply to all Medicaid state plan benefit designs; for states that did not use an MCO at all in connection with delivery of services, the proposed rule at §438.900 through §438.930 would have not been applicable. States that have individuals enrolled in MCOs and have MH/SUD services offered through FFS would, under the proposed rule, have the option of amending their non-ABP state plan to be consistent with the proposed regulations or offering MH/SUD services through a managed care delivery system (MCOs, PIHPs, and/or PAHPs) to be compliant with the proposed rules.

As noted in the proposed rule, for beneficiaries who are not enrolled in a MCO, and thus not covered by section 1932(b)(8) of the Act, this rule would not affect coverage (other than when the services are part of an ABP). However, we encourage states to provide state plan

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benefits in a way that comports with the mental health parity requirements of section 2726 of the PHS Act.

Comment: Many commenters expressed gratitude to CMS for including important language in the proposed rule encouraging states to provide state Medicaid plan benefits in compliance with parity even when they are not required to do so under the MHPAEA or regulations. Many commenters supported application of parity requirements to all benefits for Medicaid managed care enrollees, including benefits that are provided by PIHPs, PAHPs, or FFS. Some commenters recommended that CMS work closely with states to ensure that all Medicaid beneficiaries have strong coverage for MH/SUD services.

Response: We will continue to provide support and technical assistance to states to strengthen coverage of MH/SUD services for all Medicaid participants even when states are not required to do so through this rule.

Comment: Many commenters encouraged CMS to apply parity protections beyond what is required under federal law. The commenters indicated that CMS should encourage states to apply parity benefits equally for all Medicaid enrollees, regardless of whether they are enrolled in managed care, ABPs or traditional FFS. Some commenters were concerned that individuals being served entirely in the FFS environment are being denied the same protections as individuals who get some portion of their care through a managed care arrangement. The commenters maintained that the proposed rule did not promote a level playing field between managed care arrangements and FFS. In addition, the commenters stated that exempting Medicaid FFS from the proposed mental health parity requirements will create inequality in service delivery for Medicaid beneficiaries and could have serious implication for the viability of Medicaid managed care plans. A commenter suggested that requiring Medicaid FFS to comply with the parity requirements outlined in the proposed rule would allow for continuity of care,

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increased access to care and services, care coordination and improved quality of MH/SUD services for all beneficiaries.

Response: We acknowledge that this final rule does not provide the same protections to Medicaid beneficiaries receiving only FFS benefits as it does for those enrolled in MCOs. However, section 1932(b)(8) of the Act does not provide authority to apply parity protections to beneficiaries who are not enrolled in an MCO and section 1937 of the Act limits the application of parity requirements to ABPs.

While the provisions of this rule do not apply directly to the benefit design for Medicaid non-ABP state plan services, the requirements would apply to all benefits provided to the majority of Medicaid participants because that majority of enrollees are MCO enrollees. The rule, as proposed and as finalized, imposes parity requirements in terms of the total benefits package provided to MCO enrollees, regardless of service delivery system. States that have individuals enrolled in MCOs and have MH/SUD services offered through FFS will have the option of amending their non-ABP state plan to be consistent with these regulations or offering MH/SUD services through a managed care delivery system (MCOs, PIHPs, and/or PAHPs) to be compliant with these final rules. We also encourage states that have some beneficiaries not enrolled in an MCO to offer these beneficiaries the protections afforded under parity.

Comment: Some commenters strongly suggested that CMS work with states and other interested parties to find alternative means to ensuring quality and access to MH/SUD services in states that have chosen to provide those services outside of a managed care product.

Response: As indicated above, the provisions of the Act impose parity requirements in limited cases. Therefore, we can only encourage states to take the necessary actions to apply parity to MH/SUD benefits for FFS beneficiaries. States can choose to maintain these services on a FFS basis in their state plan and make the necessary changes to their state plan to comply

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with this final regulation. Nothing in this final regulation prohibits states from including additional MH/SUD services in their state plan or in managed care arrangements.

Comment: Many commenters stated that CMS's proposed mental health parity rules impermissibly encroach on states' flexibility to decide how to operate their Medicaid programs. The commenters indicated that the various delivery system arrangements that states use will become significantly more complex and difficult to administer under CMS's proposal to apply the mental health parity standards to state plan services delivered outside of a Medicaid MCO. Specifically, in some states, the administrative complexity of applying the rules to services delivered outside of an MCO may drive behavioral health services into the MCO contracts to the detriment of a longstanding, publicly operated service delivery system. Another commenter indicated that requiring that all state plan MH/SUD services to be included in all MCO contracts diminishes the state's flexibility and ability to develop new and innovative programs based on new evidence-based models. The commenter suggested that the state's flexibility to develop new models should be preserved.

Response: We disagree that the proposed mental health parity rules impermissibly encroach on states' flexibility to decide how to operate their Medicaid programs. We maintain that applying various parity provisions across the different delivery systems would allow states the most flexibility in designing delivery systems while ensuring that parity in coverage of medical/surgical and MH/SUD services is provided to MCO enrollees. Under this final rule, parity requirements apply to the entire package of services MCO enrollees receive, whether from the MCO, PIHP, PAHP, or FFS. If states carve out some MH/SUD services from the MCO contract and furnish those services by PIHPs, PAHPs, or through FFS, we are applying the parity requirements to the entire package of services MCO enrollees receive. Requiring the standards for parity to be applied to the overall package of benefits received by MCO enrollees will allow

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MCOs to comply with MHPAEA requirements without requiring inclusion of additional MH/SUD benefits in the MCO benefit package, as long as these MH/SUD benefits are provided elsewhere within the delivery system. In states where MH/SUD benefits are provided across multiple delivery systems (including FFS), states are required under §438.920(b)(1) to review the full scope of benefits provided to MCO enrollees to ensure compliance with the parity requirements. As part of complying with this regulation, we expect states to work with their MCOs (or PIHPs and PAHPs) to determine the best method of achieving compliance with parity requirements for benefits provided to the MCO enrollees. Based on the commenter noting that services may be driven into the MCO and in light of our policy in this final rule, we reviewed the proposed §438.920(b)(2) and discovered that proposed (b)(2) was written to indicate a state responsibility only when some services are carved out of the MCO. We finalize this rule without that limitation; all states, regardless of how services are delivered to MCO enrollees; have the responsibility to ensure that the program is in compliance with these requirements. We believe that because of this oversight requirement and the flexibility found in these final rules, the state should not have incentives to either move benefits into the MCO or outside of the MCO for purposes of complying with these rules. Because of these reasons we are finalizing §438.920(b)(2) in the final rule with revisions to require states to monitor the program in any instance where an enrollee is receiving benefits through an MCO.

For MH/SUD benefits offered through FFS, states would not necessarily be required to amend their non-ABP state plan to meet parity requirements, but could use their existing state plan or waiver services to achieve parity when individuals are receiving some benefits (whether MH/SUD or medical/surgical) from a MCO and also some benefits through FFS (or through PIHPs or PAHPs)). However, if a state did not have MH/SUD benefits in every classification in which medical/surgical benefits are provided across all authorities, the state would have to

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choose either to offer these services through a MCO, PIHP or PAHP or amend its state plan (or a waiver of its state plan) to include these benefits to achieve compliance with proposed §438.920(a) and (b).

Comment: Several commenters indicated that the Medicaid statute provides that each Medicaid managed care organization shall comply with the mental health parity requirements. The commenters indicated that Congress did not mean for the statute to be interpreted the way it was in the proposed rule and that only individuals that received all of their services through the MCO would be subject to the requirements in these rules. The commenters stated that CMS acknowledges the Congress' intent, but nonetheless applies the mental health parity rules more broadly based on the section 1902(a)(4) authority to provide for methods of administration that are necessary for the proper and efficient operation of the Medicaid state plan. The commenters stated that CMS cannot use its section 1902(a)(4) authority to specify Medicaid methods of administration that are inconsistent with a clear congressional directive.

Response: We disagree that this rule is contrary to the purpose of section 1932(b)(8) of the Act. We also disagree that the authority of section 1902(a)(4) cannot be employed to link the delivery systems that would furnish MH/SUD services to individuals enrolled in a Medicaid MCO to ensure that enrollees in an MCO receive benefits that are consistent with the parity standards. To ensure that the goal of parity is met and avoid incentives to carve out all MH/SUD services from an MCO contract, we are requiring, through our authority in section 1902(a)(4) of the Act to specify methods necessary for the proper and efficient operation of the state plan, that if MH/SUD state plan services are provided to MCO enrollees through a PIHP, PAHP, or under FFS Medicaid (because such services are carved out of the MCO contract scope), MCO enrollees will still receive the MHPAEA parity protections with respect to MH/SUD state plan services. We are committed to and agree with commenters' recommendations to work with states and

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other interested parties to ensure quality and access to mental health and SUD services in states that have chosen to provide those services outside of a managed care product.

Comment: Several commenters requested CMS to clarify in the final rule that only beneficiaries receiving both their MH/SUD and medical surgical benefits through a FFS delivery system are not provided parity protections.

Response: To clarify, the rule does not apply to Medicaid state plan beneficiaries who are not enrolled in an MCO, and thus, not covered by section 1932(b)(8) of the Act. However, this rule does apply to all beneficiaries enrolled in ABPs and CHIP, regardless of the benefit delivery system. We encourage states to provide all state plan benefits in a way that comports with the mental health parity requirements of section 2726 of the PHS Act.

Comment: A commenter recommended CMS develop a chart for beneficiaries, providers, authorized representatives and plans to explain which insurance arrangements must meet parity and which do not. The commenter indicated there is much confusion among beneficiaries about whether MHPAEA applies to such plans as Medicare, Department of Defense and Federal Employee Health Benefits Program.

Response: We appreciate the commenters' recommendations for CMS to provide further guidance to states on ensuring and applying parity requirements through all service delivery systems in Medicaid and CHIP programs, including to individuals receiving services as part of an ABP. We will be providing additional information and technical assistance to states and MCOs regarding this final rule. Medicare, Department of Defense, and the Federal Employee Health Benefits Programs are outside the scope of this rule.

Comment: A few commenters requested further guidance for ensuring parity for services authorized as part of a mental health rehabilitation and mental health targeted case management

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as a package of services and when services needed outside of the package are referred to the MCO organization for prior authorization.

Response: In this final regulation we are requiring states to apply parity to all MH/SUD services offered in their non-ABP state plan for individuals that are enrolled in an MCO.

As indicated throughout this final rule, we are finalizing the overall scope of the parity requirements as proposed. Specifically, the parity requirements will apply to benefits provided to MCO enrollees (regardless of the delivery system of those benefits), to ABPs and to CHIP. As discussed in the responses to comment, §438.920(b)(2) is being finalized with changes to require states to monitor the program in any instance where an enrollee is receiving benefits through an MCO.

L. Scope and Applicability of the Final Rule (§438.920(a) and (b), §440.395(e)(2), and §457.496(f)(1))

Sections 438.920, 440.395(d), and 457.496(f) of the proposed rule addressed the applicability and scope of the rule. Specifically:

- Section 438.920(a) proposed that the requirements of the subpart apply to delivery of Medicaid services when an MCO is used to deliver some or all of the Medicaid services; section 438.920(b) proposed state responsibilities when the MCO delivers only some of the Medicaid services. Section 438.920(b)(1) proposed that in the cases where some services are delivered outside of the MCO, the state must complete the parity analysis and provide evidence to the public. States completing the parity analysis must do so consistently with the parameters discussed in this rule, meaning they need to review the MH/SUD benefits to ensure they are included in the contracts with limitations or financial requirements that are no more stringent than the predominant limitations or financial requirements applied to substantially all of the medical/surgical benefits provided to the MCO enrollees. Under section 439.920(b)(2), we

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proposed that the state must ensure that MCO enrollees receive services in compliance with subpart K when the MCO did not provide all medical/surgical and mental health/substance use disorder benefits. Our proposal contemplated that these responsibilities could be met through appropriate reporting from the MCOs in order for the state to adequately oversee the program.

- Proposed §440.395(d)(1) indicated that §440.395 applied to ABPs that are not delivered through managed care.
- Proposed §457.496(f)(1) indicated that §457.496 applied to CHIP state plans, including when benefits are furnished under a contract with MCEs.

The tri-Department MHPAEA final rules state that if a group health plan or health insurance coverage provides MH/SUD benefits in any classification of benefits, MH/SUD benefits must be provided in every classification in which medical/surgical benefits are provided. Under our proposed amendments to part 438, for parity standards to apply, a beneficiary must be enrolled in an MCO, as defined in §438.2, under a Medicaid contract. Enrollment in a PIHP or PAHP alone would not be sufficient for parity to apply if a beneficiary were not also enrolled in an MCO. The proposed rule noted that whether the MCO provides medical/surgical or MH/SUD benefits under that contract is irrelevant for the MCO coverage to trigger parity requirements.

While many Medicaid MCOs are contracted to offer benefits in each of the classifications of benefits described in this rule, there are other state-initiated “carve out” arrangements (for example, PIHPs, PAHPs, or FFS) in which the MCOs are only contracted to provide benefits in one MH/SUD classification, while PIHPs, PAHPs, FFS, or a combination of all three provide coverage of benefits in other classifications; the division of coverage might be across the classifications identified in §438.910(b), §440.395(b)(2)(ii), and §457.496(d)(2) or might be based on the nature of services as medical/surgical services, mental health services or substance

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use disorder services. For example, MCOs in these carve-out arrangements could have contracts that include MH/SUD benefits in the prescription drug and emergency care classifications of benefits, but some or all of the MH/SUD outpatient or inpatient benefits may be covered instead through a PIHP, PAHP, or FFS delivery system.

In instances where the MH/SUD services are delivered through multiple managed care delivery vehicles, we proposed in §438.920(a) that parity provisions apply across the managed care delivery systems; this rule was proposed to apply for managed care delivery in the Medicaid program and in CHIP. Coverage parity requirements would apply to the entire package of services MCO enrollees receive, whether from the MCO, PIHP, PAHP, or FFS. If states carve out some MH/SUD services from the MCO contract and furnish those services by PIHPs, PAHPs, or FFS, we proposed to apply the foregoing parity requirements to the entire package of services MCO enrollees receive. Requiring the standards for parity to be applied to the overall package of benefits received by MCO enrollees allows MCOs to comply with these requirements without requiring inclusion of additional MH/SUD benefits in the MCO benefit package, as long as these MH/SUD benefits are provided elsewhere within the delivery system. In states where MH/SUD benefits are provided across multiple delivery systems (including FFS), we proposed in §438.920(b)(1) that states would be required to review the full scope of benefits provided to MCO enrollees to ensure compliance with the requirements of this rule. We noted that we would expect states to work with their MCOs (or PIHPs and PAHPs) to determine the best method of achieving compliance with these parity requirements for benefits provided to the MCO enrollees. For MH/SUD benefits offered through FFS, states would not be required under the proposed rule to amend their non-ABP state plan to meet parity requirements, but could use their existing state plan or waiver services to achieve parity when individuals are receiving some MH/SUD benefits from a MCO (including PIHPs or PAHPs) and also some benefits through FFS. However, if a

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state does not have MH/SUD benefits in every classification in which medical/surgical benefits are provided across all authorities, the state would have to choose either to offer these services through a MCO, PIHP or PAHP or to amend its state plan (or a waiver of its state plan) to include these benefits to achieve compliance with proposed §438.920(a) and (b). Applying various parity provisions across the different delivery system allows states the most flexibility in designing delivery systems while ensuring that parity in medical/surgical and MH/SUD services is provided to MCO enrollees. Given that there are many different delivery system configurations that carve out MH/SUD services, this allows compliance with parity requirements while reducing incentives for states to completely carve in all MH/SUD benefits to a MCO or carve out or terminate coverage of MH/SUD services.

In states where the MCO has responsibility for offering all medical/surgical and MH/SUD benefits, we noted in the proposed rule that compliance with our proposal would mean that the MCO is responsible for undertaking the parity analysis and working with the state on changes found to be necessary to the MCO contract for it to be compliant with parity requirements. Underlying our proposal was an anticipation that states would need to include contract provisions in these MCO contracts to make sure they can see the results of the parity analysis completed by the MCO and have adequate oversight of the program to ensure that enrollees are receiving services in compliance with these rules so they can be in compliance with the rules as amended in §438.920(b)(2). In states where some or all MH/SUD benefits are provided to MCO enrollees through PIHPs, PAHPs, or FFS, we proposed in §438.920(b)(1) that the state would have the responsibility for undertaking the parity analysis across these delivery systems and determining if the existing benefits and any financial or treatment limitations are consistent with MHPAEA. The state, based on this analysis, would have to make the necessary changes to ensure compliance with parity requirements for its Medicaid MCO enrollees. We

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also proposed in §438.920(b)(1) that the state provide documentation of its compliance with this analysis to the general public within 18 months of the effective date of this rule.

For ABPs and CHIP state plans, we proposed to require states to apply the provisions of this rule across all delivery systems to ensure that beneficiaries have access to MH/SUD benefits in every classification in which medical/surgical benefits are provided. If states offer services through an ABP or CHIP state plan with various delivery systems (managed care and non-managed care), the state must apply the provisions of the rule across the delivery systems utilized for its ABP and CHIP state plan. The proposed rule included an example of how the proposal would apply across the delivery system in Medicaid:

Example 1. Facts. A Medicaid MCO enrollee can access Medicaid benefits in the following way at any given time during their MCO enrollment:

- The MCO comprehensive benefits include inpatient medical/surgical benefits; outpatient medical/surgical benefits; emergency for medical/surgical and MH/SUD benefits; and prescription drugs for medical/surgical and MH/SUD benefits.

- The PIHP carve out benefits include inpatient MH benefit and the outpatient MH benefit.

- The PAHP carve out benefits include outpatient SUD benefits.

- The FFS system provides access to inpatient SUD benefits.

For purposes of this example, we assume there are no financial requirements or treatment limitations imposed on any of the benefits in any of the delivery systems noted above.

Example 1. Conclusion. In this example, the MCO, PIHP or PAHP would not need to add any additional services to its benefit package because the MCO enrollee has access to MH/SUD services through PIHPs, PAHPs and FFS. The state is responsible for undertaking the parity analysis across delivery systems and making sure the coverage complies with parity

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requirements under §438.920(a) and (b). The example would apply in the same way to a CHIP enrollee.

Comment: We received several comments regarding the proposal to apply the protections of MHPAEA to all MCO enrollees regardless of the delivery system for MH/SUD services. Most comments received were in support of CMS' interpretation and expressed that if CMS limited the protections of MHPAEA to apply only to the benefits provided by the MCO, this would not fulfill the intent of the law. In contrast, some commenters did not support CMS' interpretation and felt that the rule should require all services for both medical/surgical and MH/SUD conditions to be provided by the MCO, based primarily on the premise that it is easier to provide a level of care coordination that is appropriate for the needs of people requiring intensive levels of MH/SUD services if all benefits are provided by one entity.

Response: We appreciate the comments related to the application of this rule to all MCO enrollees regardless of how the MH/SUD services are delivered. We believe that our interpretation is in line with the intent of section 1932(b)(8) of the Act and allows the most flexibility to states to determine the best delivery system in their state. Therefore, we are maintaining this interpretation in the final rule. In any system that the state chooses, we recommend that the state pay close attention to the care coordination aspects of the program to ensure that medical/surgical services and MH/SUD services are coordinated and integrated to the greatest extent possible.

Comment: One commenter suggested CMS require parity compliance for all managed care entities that contract with a PIHP or PAHP to deliver behavioral health services. This would include primary care case management (PCCM) entities or providers.

Response: While we encourage states to apply parity broadly across the state plan and to any service delivery system, section 1932(b)(8) of the Act only applies MHPAEA parity

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requirements to MCOs; therefore, we cannot extend its reach to services provided to beneficiaries who do not enroll with MCOs. In situations where a state uses a PCCM program to provide medical/surgical services and uses a PIHP or PAHP to provide MH/SUD services (meaning that the state does not use an MCO at all), the state would not be required to meet the requirements in part 438 this final rule. Similarly, accountable care collaborative models using managed FFS authority such as PCCM are not considered MCO contracts under the definition provided in §438.2, and therefore, are not required to comply with part 438, subpart K. However, as noted above, we do encourage states to consider applying the MHPAEA protections to the state plan so that individuals using a PCCM will still benefit from provisions in this final rule.

Comment: Some commenters were unclear if parity requirements were applicable, and if so how those requirements would be applied, to section 1115 demonstrations and other waiver authorities. Commenters were concerned because many states use these programs to provide a variety of services to vulnerable populations or to treat specific behavioral health conditions, such as autism spectrum disorder.

Response: Parity requirements set forth in this final regulation apply to MCOs and ABP regardless of the authority a state employs for its Medicaid program. While we welcome Demonstrations and other Waivers that seek better outcomes for beneficiaries in need of MH/SUD, we believe these parity requirements are necessary to provide adequate protections for beneficiaries enrolled in demonstration and waiver programs. Therefore, we will not approve any Waivers of the parity requirements set forth in this final regulation in a request for an 1115 Waiver.

Comment: We received several comments about who should be responsible for the parity analysis in varying situations. Some commenters believed that the state should be able to

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delegate the responsibility to other parties when using a carve-out system, such as the entities themselves or county agencies, whereas other commenters believed that the state Medicaid Agency should be the sole party completing the parity analyses, even in the case where the MCO is providing all medical/surgical and MH/SUD benefits within its contract. Some comments expressed concern that even in the case of a carve-out system, the MCO will end up needing to do the parity analysis, which commenters believe will create delays in the 18-month timeline for compliance.

Response: We considered affording the state the option of choosing who would have responsibility for the parity analysis in situations when the MCO does not provide all MH/SUD services, but we were concerned about the timeliness and consistency of the parity reviews if the state was not responsible for this analysis under the regulation. Therefore, we are finalizing text in §438.920(b)(1) to require the state to perform the parity analysis when the MCO is not providing all MH/SUD services to Medicaid beneficiaries; this is the scope and intent of the regulation text requiring states to review all services to ensure compliance with the rule and implicit in the requirement for the state to provide documentation of that compliance. The state may use third parties to gather information and make a preliminary parity analysis on its behalf, but the state must review and accept that preliminary analysis. And, the state will be responsible for providing documentation supporting compliance with these rules when submitting the MCO contracts to us for review and approval. To the extent that a state chooses to use contractor or other resources to complete the analysis, we would expect the state to answer any questions about the analysis and we will hold the state accountable for its accuracy and completeness.

When the MCO provides all medical/surgical and MH/SUD benefits, the statute imposes the parity compliance on the MCO. It is implicit in our final rule, at §438.920(a), that the MCO perform the analysis in those circumstances. We believe that states should be aware of the

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timeframe for completing the parity analysis and the outcomes when the MCO does it to be sure the state oversees the delivery of benefits in a manner that is compliant with these rules, including implementing any appropriate contract changes. States should be sure to include contract provisions in their MCO contracts in these cases to be sure they get the necessary reporting during the 18-month implementation period.

Comment: One commenter stated that, in cases where an MCO does the parity analysis, the MCO could simply provide an assurance of compliance. This commenter noted that the proposed rule did not require the MCO to tell the state Medicaid Agency what changes needed to be made to their contracts, and that the state Medicaid Agency would need to determine those changes based on their regulatory oversight.

Response: While we agree that the final rule does not require specific documentation from the MCOs when they complete the parity analysis, we believe that it would be in the interest of the states to require the MCOs to report the findings and the analysis that they complete. We encourage states to include contract provisions that they believe are necessary during the implementation period to get the information necessary to make changes to the contract that would demonstrate compliance with these rules. We are not including any additional regulatory reporting requirements in this rule as we believe states should be at liberty to collect the appropriate reporting they deem necessary for the oversight and implementation of their programs consistent with these requirements. We are available to help states consider contract language to achieve this if necessary during the 18 month transition period.

Comment: The proposed rule would have required states to provide documentation to CMS with their contract submission in cases where some or all MH/SUD benefits are provided to MCO enrollees through PIHPs, PAHPs, or FFS. We received several comments requesting guidance on what documents must be provided with contracts and state plan amendments to

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document compliance with the requirements of this rule. Some commenters requested that these documents be required to be submitted on an annual basis. Commenters also raised concerns about situations where the MCO provides the full scope of services, stating that an assurance of parity compliance from the state in these cases is insufficient and creates inconsistency in documentation of compliance requirements. Another commenter requested that CMS provide technical assistance to states as they complete their parity analyses in order to give “best practices” in determining compliance.

Response: We will provide technical assistance and tools for states and MCOs that clarify expectations around the types of documentation that must be submitted with the MCO contracts and ABP state plan amendments to demonstrate compliance with parity. MCO contracts are typically submitted on an annual basis, and should include materials that demonstrate that the state is confident in the parity analysis. We do not believe that the parity analysis needs to be completed on an annual basis if the state can show that the plans or state did not change their operations in a way that would affect compliance with this rule. We will use the submitted documentation as part of our MCO contract review and approval process. As noted in a previous response, states should consider including provisions in their contract for MCOs to report on the outcome of the parity analysis to ensure that parity is achieved and can be overseen appropriately. States may want to consider requiring the MCOs to complete the analysis in a way that is consistent with how the state completes the analysis for its ABP or CHIP state plans.

Comment: We received some comments noting that, in the proposed rule, states were only required to review MH/SUD services to ensure the full scope of services meets the requirements. Commenters believed that states need to review both the medical/surgical criteria and the MH/SUD criteria to determine full compliance with this rule. |

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Response: We agree with the commenters, and in the final rule we have revised to §438.920(b)(1) to provide that the state must review both medical/surgical and MH/SUD benefits provided to determine compliance with the final rules where in the proposed rule we only indicated that the state would review the MH/SUD benefits. States should consider including contract provisions in all MCO and applicable PIHP and PAHP contracts to achieve this requirement.

Comment: One commenter expressed concern over the term “scope of services,” citing the fact that it has become a term of art within the context of parity and may be misconstrued when reviewing the regulation text in §438.920(b).

Response: We appreciate that “scope of services” may have different meanings in different contexts, but we believe that for the purposes of this regulation, it is sufficiently clear that we mean the full set of benefits available to the Medicaid beneficiary.

Comment: We received several comments that requested that CMS require states to publicly report on the progress of compliance during the 18-month period between the publication date of the final rule and date of compliance, and to make sure states engage the public on the progress towards compliance with the requirements of this rule. Several commenters urged CMS to develop a common methodology for federal and state regulators to provide identifiable transparent information on parity compliance investigations to encourage uniform compliance practices. Commenters requested that CMS post the compliance plans on Medicaid.gov and on state Medicaid websites, and to closely monitor states on their progress.

Response: To make compliance information available to the public more quickly, and to simplify compliance deadlines across requirements for MCOs, ABPs, and CHIP, we have changed the date by which states must provide such information from 18 months from the effective date of the final rule to 18 months from the publication date of the final rule. Because

the provisions of the final rule do not become effective until 60 days after publication, this change will ensure that information regarding states' compliance with this subpart becomes available to the public in a timely manner.

As specified in §438.920((b)(1) of this final rule, states must make documentation available to the public within 18 months after the publication of this final rule about compliance with these rules; this means that states must report how they are complying in order to document compliance. We have clarified in the final regulation at §438.920(b)(1) that this documentation must be updated when benefits change.

We do not require through regulation that states consult with stakeholders on how to comply with these rules because in doing so we believe we would have needed to specify how and when that public input process occurred which could create further delays in the implementation timeline, making it longer than 18 months. Although we are not requiring states to work with stakeholders and other public interests to determine the best way to comply with these rules, we believe that states will need to discuss options with stakeholders in their current delivery systems to be able to ascertain the best delivery system for any additional benefits that may be required. We also encourage states to have discussions with stakeholders other than their providers and plans to ensure they achieve compliance in the best way for their beneficiaries. We do not believe we also need to post the materials on Medicaid.gov, as states will be posting their documentation on their own websites. Posting on state websites is more targeted and would be more effective in facilitating discussions with the stakeholders in that state. We are not mandating the use of a common methodology for state oversight of parity compliance, given the diversity of approaches that states use to structure their treatment delivery systems, and given our desire to provide states flexibility to tailor their administrative processes to the context and needs

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in their state. However, as noted in other sections, we will make technical assistance available to states that wish to discuss compliance strategies.

Comment: We received comments about the use of a website for the location of where states make the documentation of compliance available to the public. One commenter noted that the use of a website would be too administratively burdensome on states and questioned why this particular provision would be called out when others do not require to be posted on a state's website. Another commenter requested that CMS clarify in the text of the regulation that the state must use a website, noting that the proposed language only indicates that the state must make the documentation available but did not specify the location.

Response: We believe that the use of a website operated by the state is consistent with other managed care proposed rules and in line with other requirements. Therefore, we are modifying the regulation in this final rule to require, in §438.920(b)(1), that the documents demonstrating compliance must be made available to the general public through the state's website.

As indicated in the response to comments here and in other sections, we are finalizing these provisions in §438.920(a) and (b), §440.395(e), and §457.496(f)(1) as proposed with several revisions. We revised §438.920(b)(1) to clarify that the state must review both medical/surgical and MH/SUD services delivered to MCO enrollees to determine compliance with the final rules and we revised §438.920(b)(2) to clarify that the state needs to complete oversight to ensure enrollees receive services in compliance with these rules in every instance that there is an enrollee of an MCO. The requirements of §457.496(f)(1) were also modified to require states to indicate in their state plan the standard used, such as state guidelines or the most current versions of the DSM or ICD, when classifying benefits into their respective category as a medical/surgical, mental health, or substance abuse disorder benefit. The intent of this

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requirement is to capture this information within the state plan in order to increase transparency and facilitate our understanding of the state's parity analysis during our review of their compliance SPA. Furthermore, the collection of this standard is consistent with the approach taken in CHIP to describe other required benefits provided in separate CHIPs. We are also finalizing §438.920(b)(1) with a change in the date by which the state must publish the documentation of its compliance with part 438, subpart K and a requirement for the state to update its analysis and documentation.

M. Scope of Services (§438.920(c), §440.395(e)(2), §457.496(f)(2))

In the proposed rule, we included provisions relating to the scope of the parity requirements for Medicaid MCOs and CHIP state plans that were similar to the provisions set forth in the MHPAEA final regulations (§146.136(e)(3)). Specifically, the proposed regulations did not require a MCO, PIHP, or PAHP to provide any MH/SUD benefits for conditions or disorders beyond the conditions or disorders that are covered as required by their contract with the state. For MCOs, PIHPs, or PAHPs that provide benefits for one or more specific MH conditions or SUDs under their contracts, the proposed regulations did not require the MCO, PIHP, or PAHP to provide benefits for additional MH conditions or SUDs. The proposed regulations did not affect the terms and conditions relating to the amount, duration, or scope of MH/SUD benefits under the MCO, PIHP or PAHP contract except as specifically provided in §438.905 and §438.910 of part K. For states providing benefits through ABPs, we clarified in proposed §440.395(d)(2) (which is being re-designated as §440.395(e)(2) in this final rule), that §440.395 does not require a state to provide any specific MH/SUD benefits; however in providing coverage through an ABP, the state must include EHBs based on the applicable EHB reference benchmark plan, including the ten EHBs specifically required in §440.347.

Comment: We received comments requesting that CMS strengthen its requirements around prescription drug coverage for MH/SUD conditions and require that the full range of mental health and addiction medications approved by the FDA must be covered.

Response: Under Federal Medicaid law, states are required to comply with the requirements of section 1927(g)(1) of the Act to the extent that they provide assistance for covered outpatient drugs under their Medicaid FFS programs or Medicaid managed care plans. Therefore, states are required to provide coverage of all drugs that meet the definition of covered outpatient drugs as outlined in section 1927 of the Act, when such drugs are prescribed for medically accepted indications, including those indicated for the treatment of mental health conditions and substance use disorders. Consistent with section 1927(d) of the Act, state Medicaid FFS programs and Medicaid managed care plans have the discretion to establish certain utilization management techniques that include preferred drug lists and prior authorization processes for the coverage of covered outpatient drugs.

However, under the requirements of this rule, a regulated entity may not impose NQTLs (including prior authorization or other utilization management strategies) for drugs used to treat MH/SUD conditions unless any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to the MH/SUD benefit are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the same classification. Similarly, under certain circumstances, regulated entities may apply different levels of financial requirements and treatment limitations to different tiers of prescription drugs and still satisfy the parity requirements. Regulated entities may subdivide the prescription drug classification into tiers based on reasonable factors as described in this rule and without regard to whether a drug is generally prescribed for medical/surgical benefits or for MH/SUD benefits.

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Comment: We received a few comments that wanted CMS to encourage states to cover MH/SUD services through a broad range of providers as a way to ensure adequate access to services.

Response: Although we believe that this comment is outside the scope of this rule, we have issued guidance over the past several years and provided states with information to encourage access to mental health and substance use services, including clarifications regarding additional agencies and practitioners that can render MH/SUD services.

Comment: One commenter expressed concern with language at §438.920(c)(1) that stated that MCOs are not required to provide any services beyond what is described in their contract. This commenter believed that this could provide a loophole for MCOs looking to reduce benefits.

Response: We included this provision based on the ability of the state to determine compliance with the requirements in Subpart K of 42 CFR part 438 across multiple delivery systems. If a state is using a PIHP, PAHP, or FFS benefits to comply with these rules, the MCO should not also have to provide additional benefits on the basis that its contract, on its own, does not comply with the requirements in this subpart. We believe that other areas of 42 CFR part 438 protect against the MCO arbitrarily reducing benefits, most notably §438.210, which provides that the MCO may not arbitrarily deny or reduce the amount, duration or scope of a required service solely because of the diagnosis of a beneficiary.

As indicated in the response to comments, we are finalizing the provisions regarding scope of services at §438.920(c), §440.395(e)(2), and §457.496(f)(2) as proposed.

N. Increased Cost Exemption

The proposed rule did not include an increased cost exemption for MCOs, PIHPs, or PAHPs. However, the proposed rule did include changes to payment provisions in part 438 to

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allow states to include the cost of providing additional services or removing or aligning treatment limitations in their actuarially sound rate methodology where such costs are necessary to comply with the MHPAEA parity provisions. These proposed changes to the managed care rate setting process would give states and MCOs the ability to fully comply with these mental health parity requirements by giving them flexibility to provide services compliant with this regulation or remove or align service limits. We stated that the Medicaid program rather than the plan should bear the costs of these changes, and proposed to provide up to 18 months after the date of the publication of the final rule for states to establish compliance with the provisions of this final rule (see discussion in section P: “Applicability and Compliance”). This would allow states to take the actions to make the policy and budgetary changes needed for compliance. The proposed rule also excluded permission for states delivering services through an ABP or CHIP State plan to apply for a cost exemption due to the mandatory delivery of EHB and the requirement that ABPs be compliant with MHPAEA.

Comment: Many commenters agreed that an increased cost exemption for parity was not needed. The commenters supported building in increased costs associated with parity into the state’s rate setting structure. In addition, the commenters recommended that the regulation require a behavioral health medical loss ratio of 90 percent for clinical services, MH/SUD services and activities that improve health care quality in their MCO contracts. One commenter recommended that CMS allow cost exemptions for administrative expenses to MCOs in instances where states may not develop rates that adequately support the additional care management and coordination required to ensure compliance with parity requirements.

Response: We affirm that this rule does not include an increased cost exemption for MCOs, PIHPs, or PAHPs. We do not expect Medicaid managed care entities to incur any net increase in costs because we are finalizing a provision stating that the costs of complying with

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parity requirements may be taken into account within an actuarially sound payment methodology. However, recommendations regarding requirements for medical loss ratios or reimbursement rates are beyond the scope of this final regulation.

Comment: Many commenters disagreed with denying states access to a cost exemption. The commenters maintained that MHPAEA allows group health plans and insurance issuers to seek a cost exemption, and the Medicaid statute specifies that the mental health requirements apply to Medicaid MCOs, ABPs, and CHIP “insofar as such requirements apply and are effective with respect to a health insurance issuer that offers group health insurance coverage,” or “in the same manner as such requirements apply to a group health plan.” The commenters explained that there was no basis for CMS to apply MHPAEA to Medicaid and CHIP, but then for CMS to refuse to apply MHPAEA's cost exemption provision.

The commenters suggested that although MCOs may receive increased capitation payments to comply with the parity requirements in this final rule, there is still an increased cost for the state (and the federal government). In addition, the commenters indicated that it does not make sense to prevent ABPs from accessing the cost exemption simply because they must cover EHBs and must comply with parity requirements. The commenters reasoned that Federal law also requires commercial group plans to comply with MHPAEA, and it requires commercial small group and individual plans to cover EHBs, but that does not exclude them from seeking for a cost exemption under MHPAEA. The commenters applied the same logic to CHIP.

Response: As we proposed, we are not extending the cost exemption provision to MCOs, PIHPs, PAHPs, or states. We require MCOs to be paid on an actuarially sound basis, which would include the cost of adding services or removing or aligning treatment limitations in managed care benefits so long as those additional benefits are necessary to comply with mental health parity requirements. States have the ability to make changes to their capitation payments

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during the course of the contract year to account for unexpected changes in benefits, costs, and utilization if they find that the assumptions included in the initial rate development are different than actual experience. This final rule authorizes states, in instances where they choose not to change their state plan, to include the cost of services that are necessary to comply with this rule but are beyond what is specified in the state plan into the development of actuarially sound rates. This is different from the circumstances of the commercial market and removes the rationale for an increased cost exemption for Medicaid MCOs, PIHPs, and PAHPs. States may also choose to use a risk mitigation strategy in their rates the first year(s) that the additional benefits are added to a MCO, PIHP, or PAHP contract. This would ensure that any over- or under-payments are reconciled at the end of the year and give the state a more accurate sense of the utilization of services for future years of rate setting.

As indicated in the response to comments, as proposed, we do not include provisions in the final rule for an increased cost exemption.

O. Enforcement, Managed Care Rate Setting (§438.6(e)) and Contract Review and Approval (§ 438.6(n))

Proposed §438.6(e) allowed a state's rate-setting structure to account for services covered by an MCO, PIHP, or PAHP in excess of services and/or treatment limits that are listed in the State plan if such services are necessary for the MCO, PIHP or PAHP to comply with this rule. However, the proposed rule only allowed the state to adjust its capitation rates to provide for additional services to the extent that these services would not be included but for the requirements of this rule.

Proposed §438.6(n) required states to include contract provisions requiring compliance with parity requirements in all applicable MCO, PIHP, and PAHP contracts. We noted that we expected states, in order to comply with the proposal, to include a methodology for the MCO,

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PIHP, or PAHP to establish and demonstrate compliance with parity requirements within the contracts. This methodology would have to provide a mechanism for all MCOs, PIHPs, or PAHPs included in the delivery system to work together to ensure that any MCO enrollee in a state is provided access to a set of benefits that meets the requirements of this rule regardless of the MH/SUD benefits provided by the MCO. If it was not shown through the MCO contract itself that an enrollee has access to parity-compliant MH/SUD services in each classification in which medical and surgical services are provided, the state would be asked to provide supplemental materials to the MCO contract or an amendment to the contract to demonstrate that the standards provided here are met.

If a state did not adequately demonstrate that an MCO's contract and practices are in compliance with the proposed rule, CMS proposed to defer federal financial participation (FFP) on expenditures for the MCO contract because compliance with section 1932 is a requirement for FFP payment under section 1903(m)(2)(A)(xii) of the Act. Where there are services outside of the MCO contract that are needed to demonstrate compliance, the state would be required to show how the MCO enrollees are provided all the services needed to comply with the requirements in this rule.

Comment: We received a number of comments in support of CMS's proposal to allow states to include the costs of coming into compliance with the requirements of this rule into the actuarially sound capitation rates paid to the MCO, PIHP or PAHP providing MH/SUD services under §438.6(e). One commenter noted that CMS can use its review and approval of managed care contracts to ensure FFP is being used solely for state plan items and services and those services necessary to satisfy the parity requirements. Commenters further stated that they believe the costs of coming into compliance will be minimal, and over time may save money as timely access to MH/SUD services may reduce the need for costly emergency and crisis care.

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One commenter added that this was an opportunity for plans to enhance care coordination, to the extent that these requirements ensure access to a wider range of specialists than previously covered. Some commenters requested that CMS require states to include the cost of any additional services in §438.6(e)(3) rather than providing states the option to adjust these rates. Other commenters believed that the language was too broad and CMS should follow the guidance issued in the 2013 State Health Official letter which encouraged states to make changes to their state plan. Finally, others thought that the language was sufficiently clear and strongly requested that CMS refrain from adopting more prescriptive language regarding what additional benefits may be included because it is clear that the services need to be included to ensure parity.

Response: We believe that allowing capitation rates to reflect additional compliance costs related to non-state plan services was necessary for plans and states to meet the requirements of Subpart K when changes to the Medicaid state plan are not required by federal law. We do not agree that it is necessary to explicitly amend §438.6(e)(3) as suggested by the commenter to achieve this result, because we believe it will be inherent in 438.6(n). If services are necessary beyond what is included in the state plan to ensure compliance with this rule, states and their actuaries must take the expected reasonable and appropriate cost of those additional services into consideration while setting actuarially sound rates. In addition, as noted in other areas of the rule, states have the flexibility to include those additional services either through the MCO, PIHP, or PAHP benefit package, or they can add them to the state plan by completing a state plan amendment. To make the payment rate adjustment under §438.6(e)(3) a requirement could prohibit states from making changes to their state plan which could allow for a broader application of parity than is required through this rule.

Comment: We received several comments requesting model contract language that states can use to be able to demonstrate compliance with these rules. Contract language is requested to

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clarify which additional MH/SUD services plans would be required to provide when a carve-out approach is used, and to require states to reimburse the plan in an actuarially sound manner.

Response: Considering there are a number of different models the states can choose to demonstrate compliance, we would not be able to provide model contract language for every situation. However, we are working with a contractor to develop technical assistance materials, and we are available to states during the transition period if states would like to discuss their plans for compliance and possible contract language.

Comment: We received a number of comments requesting CMS to provide more clarity on what documentation it expects states to provide to show that it complies with the regulations when submitting MCO contracts.

Response: We will release subregulatory guidance around documentation that will be required to show compliance with these regulations. Additionally, we are working with a contractor to develop tools and provide technical assistance to states in completing the analysis of their delivery systems to ensure the benefit design and medical management techniques meet the requirements of these rules.

Comment: We received some comments requesting CMS clarify its role in oversight of these regulations and urged CMS to improve enforcement in the commercial market, as well as for Medicaid and CHIP.

Response: Oversight of commercial products and compliance with the tri-Department MHPAEA final rules are outside the scope of this final rule.

As with other Medicaid MCO contracts and state plan amendments, we will review associated and relevant documents submitted by the state. This will include the review of the MCO contracts and SPA documents, as well as any documentation of the parity analysis the state has done to determine that their system and/or benefit design meet the requirements of this rule.

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States will be the primary oversight entity to ensure that services are delivered in compliance with these rules. Beneficiaries and/or stakeholders should first direct any issues related to compliance with this rule to the state. We are willing to accept complaints around compliance with this rule and we may discuss these issues with states to determine if any corrective actions need to take place.

Comment: There were several comments that CMS should specify that CMS, states, MCOs, PIHPs, and PAHPs pay particular attention to MH/SUD parity requirements for children and adolescents as a distinct population group. The commenters encouraged CMS and states, when assessing compliance with these rules, to obtain input on delivery of services from child and adolescent MH/SUD providers, including pediatric medical providers. In addition, the commenters strongly suggested CMS regularly monitor pediatric MH/SUD network adequacy, access standards for children and adolescents (including inpatient admission), EPSDT service coverage mandate and prior authorization criteria, data showing the number of reasons for child and adolescent denials, and pre- and post-utilization patterns by children of intensive home and community based services, and inpatient MH/SUD services.

Response: This final rule does not create specific oversight requirements for distinct population groups, nor does it provide for access reviews to needed services. States are required to ensure compliance with the requirements of this rule for all enrollees whose benefits are subject to this rule. However, we will provide technical assistance to states upon request to assist with the implementation of this rule. If questions or confusion persist about the requirements of this rule for pediatric populations, we may provide tools or guidance to respond to those questions. CHIP and ABP programs that include full coverage of EPSDT, in the same manner as in regular Medicaid coverage, will be deemed compliant with this rule in accordance with the statutory authority. However, we will review a state's assurance carefully as a part of the CHIP

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or ABP SPA review process to ensure compliance with all EPSDT requirements, including the methods and procedures for implementing the EPSDT benefit. We also anticipate providing clarification through subregulatory guidance to states about the proper implementation of the EPSDT benefit. With regard to the comments on the issue of monitoring access to services that issue is outside the scope of this final rule. We are engaged in separate rulemaking to strengthen state and federal reviews of beneficiary access to needed services.

Comment: We received a number of comments that requested CMS strengthen its oversight role of the rate setting process to ensure that rates are set on an actuarially sound basis when services beyond the state plan are included. These comments included a variety of suggested approaches and requirements, including: not requiring MCOs to cover additional services until actuarially sound rates are in place; greater transparency about how states will accommodate the additional costs of compliance in their rate setting approaches; requirements that rates be set based on the specific benefit set instead of a historical look-back; development of a template that translates service changes into rate-setting formulations; annual end-of-year reconciliations of the increased costs associated with the additional benefits added to be in compliance with this rule compared to capitation rates; requiring states to consult with MCOs to select appropriate proxy data prior to development of the capitation rates; or requiring a robust analysis of past and projected claims experience.

Response: We believe that these comments stem from a perceived lack of transparency on the rate setting process in general, and that the majority of these concerns are not specific to this rule. These issues are beyond the scope of this rule; we note that we are working to increase the transparency and oversight of Medicaid managed care rate setting. We believe that the suggestions included in the comments are all helpful, but that no single approach will be appropriate for all states, and therefore, decline to require a specific methodology for including

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additional services required by parity into the capitation rates. States should work with their MCOs, PIHPs and PAHP as well as their actuaries when they develop their rates, which are required to be actuarially sound.

Comment: One commenter expressed concern that the rate setting provisions in this rule may limit states' ability to pursue innovation, and stated that states should remain free to continue to allow MCOs to provide additional non-covered services, in-lieu of covered benefits, or value added additional benefits with their savings.

Response: We do not believe that this rule limits a state's ability to pursue innovation by allowing MCOs to offer additional services not specified under the state plan or contract, commonly referred to as in-lieu of benefits or value added benefits. States and MCOs are still permitted to provide these benefits under this rule. This final rule only specifies that states must include the cost of additional benefits necessary for compliance with parity in the capitation rate development process. Comments about the rate setting process in general are outside the scope of this final rule.

Comment: CMS should articulate penalties for violations of parity and publish announcements about the remedies implemented and sanctions imposed to deter parity non-compliance.

Response: In the proposed rule and as remains in the final rule, where there are services outside of the MCO contract that are needed to demonstrate compliance, the state is required to show how the MCO enrollees are expected to receive all the services needed to comply with the requirements in this rule. States would be able to do this by providing evidence of the other services provided through a FFS system, or included in contracts with other types of managed care entities such as through a PIHP or a PAHP. We would also expect that the state provide the analysis that shows services provided through the MCO meet the requirements of this final rule.

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We clarify our intent that this demonstration would be a precondition to CMS approval of the MCO contract under §438.6. If the state cannot provide evidence of this compliance outside of the MCO contract, then the state has not demonstrated that the contract complies with parity requirements and we will not approve the contract until evidence of compliance is provided. We may defer claims for FFP in expenditures for capitation rates paid based on unapproved MCO contracts in this circumstance.

Comment: Some commenters expressed concern about the potential to defer FFP on MCO contracts when a carve-out delivery system is in place and the MCO is not the party that is determined to be out of compliance. These commenters requested that in these cases states be required to continue to pay the contracting plan actuarially sound capitation payments.

Response: Payment obligations under contracts between the state and the MCO are governed by state law, and contracts are subject to CMS approval. States and plans will want to discuss payment arrangements to ensure both parties understand if and when payments to the MCOs may or may not be paid which could include instances where a compliance issue with these rules is discovered either in the MCO contract or another delivery system that the MCO enrollee receives services from.

Comment: Several commenters recommend that CMS instruct states to establish specific capitation rates for children and adolescents due to concerns about assuring network participation for appropriate providers for that age range, recognizing other pediatric providers not typically considered MH/SUD providers, and accounting for appropriate utilization of MH/SUD services through EPSDT in those specific rate cells.

Response: Current rules, at §438.6(c)(3)(iii), require that when states set actuarially sound rates they must apply rate cells by eligibility category, age, gender, locality and risk adjustment or explain why they are not applicable. We do not require states to use a specific rate

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cell structure when developing their rates for MCOs, PIHPs, and PAHPs. States will want to consider all factors of their program when determining their rate cell structure and ensure that it is done in compliance with the managed care rules and in consideration of anticipated utilization of a benefit package in compliance with this final rule.

Comment: We received several comments about care coordination when states are using a carve-out system. This includes ensuring there is appropriate care coordination with providers of all types, including pediatric primary care providers, other managed care entities, and MH/SUD providers. Commenters urged CMS to consider care coordination as service costs to ensure they are included in the costs when developing actuarially sound capitation rates.

Response: Care coordination is typically considered part of the non-benefit costs when developing actuarially sound capitation payments, though states have some ability to include care coordination as a service if they include targeted case management in the benefit package. When states develop their non-benefit costs, including care coordination, states should consider the costs directly related to providing the services covered by the contract. Additionally, when states include targeted case management as a benefit, they must adequately price the service. Requiring states to account for care coordination as a service is outside the scope of this regulation.

Comment: Some commenters requested that CMS provide additional guidance on care coordination with pediatric primary care providers and how states should require their plans to coordinate with these provider types.

Response: We do not believe there is any one way to provide appropriate care coordination for individuals with MH/SUD conditions. However, we do agree that when services are better coordinated and all providers caring for the individual are informed of treatment planning, the beneficiary is likely to have better outcomes. Therefore, we encourage

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states to include contract provisions to ensure that MCOs, PIHPs and PAHPs work to coordinate among themselves and with providers to deliver an integrated set of benefits to enrollees. For more detail regarding care coordination in a Medicaid managed care environment, please refer to §438.208.

Comment: We received several comments requesting that CMS prioritize oversight and transparency in the delivery of services, including pharmacy services and formulary design/benefit tiering. Commenters requested that CMS carefully monitor claims data to quickly identify and remedy any problems.

Response: States provide the first level of oversight under this rule, and we expect states to monitor all aspects of service delivery to ensure compliance with this rule. We are always available for technical assistance to states for assistance in monitoring and if necessary to develop corrective action plans if issues are identified. In addition, we will review all areas of compliance with this rule, including whether the delivery of pharmacy services is compliant with parity requirements. As with other service classifications under this rule, states will be required to provide evidence that covered pharmacy benefits meet the requirements of this rule. We may consider using data reported through CMS claims and encounter data reporting systems to monitor service delivery, and we will work with states if any issues are identified.

Comment: Some commenters expressed concern that plans and states may put in place additional administrative measures or limits on medical/surgical benefits as a way to comply with these rules. Commenters requested that we put in place a maintenance-of-effort provision, or a requirement that states and plans can only comply with this rule by reducing restrictions on MH/SUD services to ensure that plans are not able to use administrative processes to deny access to services.

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Response: MCOs must provide benefits in the same amount, duration, and scope as the benefits offered under the state plan. States may have some restrictions on services provided under their state plan, particularly services that are optional. If a state chooses to reduce or restrict the amount, duration or scope of covered medical/surgical services it must do so through an amendment to its state plan. When reducing benefits in the state plan, a state must meet sufficiency requirements, so any reduction in medical/surgical benefits must be reviewed and approved by CMS. Consistent with the experience we have seen in the commercial market around reductions of benefits, we believe that states will not typically choose to go through the state plan amendment process to reduce medical/surgical benefits in order to make it easier for MCO coverage to meet the requirements of this rule. As some commenters noted previously, states may also realize savings over time because of increased access to MH/SUD services.

Comment: One commenter requested that CMS undertake an annual state-by-state analysis of benefit packages to determine that states and MCOs are in compliance with the requirements of this rule.

Response: Although we agree that regular monitoring of the provisions of this rule is important, we do not agree that this needs to be done on an annual basis. All managed care contracts must be reviewed and approved to be in compliance with these rules. However, mature programs do not make frequent changes in their operation that would cause them to come out of compliance with this final rule. We may ask a state to affirm that the delivery system is still in compliance at any time, including during the state plan amendment process and annual contract reviews; further we will undertake reviews as needed. However, states will be permitted to attest that there are no changes in benefit design or requirements that affect parity compliance.

Comment: A few commenters requested that additional reporting requirements be included to increase health plan transparency and enhance enforcement for NQTLs.

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Response: We believe that sufficient guidance exists regarding the recording of NQTLs in plan materials to provide transparency to beneficiaries and the public. We will make technical assistance available to states to help them develop strategies for providing proper oversight of parity requirements regarding the application of NQTLs to MH/SUD benefits.

Comment: One commenter requested that CMS require states to share with MCOs the methodology the state used to determine that the delivery system was in compliance with this rule.

Response: As states will be required to report publicly, under §438.920(b)(1), how they are complying with the requirements in this final rule in cases where not all benefits are provided through the MCO, we believe that MCOs will be able to see the information just as other stakeholders do. As plans in that delivery system (such as MCOs, PIHPs and PAHPs) will be reporting information to the state for the state to complete the analysis, the plans will have an opportunity to discuss the methodology with the state to report information; we anticipate that discussions will occur as the nature and extent of the analysis will determine the nature and scope of the underlying data needed from plans. We do not believe our regulation should require states to share the methodology with the plans just as we are not requiring the MCOs to share their methodology with the state in instances where all benefits are provided through the MCO through this rule.

Comment: One commenter was concerned that CMS did not propose to include additional administrative funding within the capitated rate setting process to cover the costs of providing the additional services through the MCO, PIHP or PAHP.

Response: As part of an actuarially sound rate setting process, states should cover the costs of providing what is included in the contract. If a state believes that additional administrative funding is necessary on the part of the MCO, PIHP or PAHP to provide any

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additional services necessary to comply with this rule, those costs should be included as part of their regular rate setting process.

Comment: One commenter requested that CMS revise §438.6(n) to state that contracts must “specify that services must be provided in compliance with Subpart K” as opposed to requiring that they “ensure that enrollees receive services that are compliant with subpart K.”

Response: We agree that the use of “ensure” when discussing contract provisions is not consistent with other provisions in §438.6 and that it is more appropriate to target the requirement on the provision, rather than the receipt, of services. To be consistent with the phrasing throughout §438.6 and to address the commenter’s concern that a contract cannot ensure that appropriate services are received, we are finalizing §438.6(n) with modifications to state that contracts must provide for services to be delivered in compliance with subpart K.

Comment: One commenter encouraged state departments of insurance to take a stronger role in monitoring parity compliance. For example, the commenter requested that a report be made to the state department of insurance when a plan has medical necessity criteria that are more stringent than generally accepted medical standards.

Response: We believe that states may choose to use a number of ways to monitor compliance with these rules. A state Medicaid agency may choose to use the state department of insurance to help monitor compliance, but we are not requiring this approach. It is not within the scope of this final rule to address how state departments of insurance may have a role in monitoring compliance by private insurers or group health plans with the tri-Department MHPAEA rules.

Comment: One commenter requested CMS postpone the application of these rules until there is an opportunity for stakeholders to comment on the combined impact of these changes with the proposed changes to rate setting requirements included in the proposed rule titled

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“Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability” (80 FR 31098 through 31297) .

Response: We do not believe that an opportunity for states and stakeholders to comment on the combination of these two proposed rules is needed. The changes proposed to Medicaid managed care rate setting in the proposed rule entitled “Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability” (80 FR 31098 through 31297) are intended to increase the overall transparency of the rate setting process and should not impact the specific provisions of this rule. We have included the rate setting provisions that are specific to compliance with parity standards in this final rule.

Comment: One commenter requested that CMS broaden the scope of the payment for services to MCOs so that it also includes payment to providers.

Response: We believe that payment to providers is addressed through our discussion of NQTLs in this rule. Payments for services are negotiated between the health care provider and the MCO, PIHP, or PAHP, and plans and providers have the autonomy to negotiate payment rates so long as they are adequate to cover services in an amount, duration and scope that is at least equal to what is provided in the state plan which is consistent with §438.210.

As indicated in the response to comments, we are finalizing the provisions regarding enforcement and managed care rate setting at §438.6(e) and the provisions regarding contract review and approval at §438.6(n) as proposed, with the exception of the revision in §438.6(n) to target contract requirements on the provision, rather than the receipt, of services.

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P. Applicability and Compliance (§438.930, §440.395(d), §457.496(f))

The proposed rule noted that MCOs, PIHPs, PAHPs, and states would have up to 18 months after publication of the final rule to establish compliance with the provisions of the final rule before we would take enforcement action. Specifically, we proposed as follows:

- Managed care: Although the requirements of MHPAEA have applied to Medicaid MCOs through section 1932(b)(8) of the Act since 2008, for Medicaid MCOs, PIHPs, or PAHPs with existing contracts, states would have to establish compliance with the specific provisions in this final rule no later than the beginning of the contract year starting 18 months after the publication of the final rule. New managed care contracts, or amendments, would be required to be compliant.

- ABPs: Although the requirements of MHPAEA have applied since January 1, 2014, states would have up to 18 months after the publication of the final rule to establish that its ABPs are compliant with provisions in the final rule.

- CHIP: The requirements of MHPAEA have applied to CHIP since October 1, 2009, however, states would have up to 18 months after the publication date of the final rule for CHIP plans to establish compliance with provisions in the final rule.

Comment: Commenters recommended a range of timeframes for states to come into compliance with these final regulations from 6 months to 24 months. Many of these commenters suggested that states that illustrate that they are making a good faith effort at compliance should be granted an extension no matter what the final rule states in terms of timeline for compliance. Several commenters noted that they believed the 18-month timeline would be sufficient to come into compliance. One commenter noted that the rules lacked a timeline for CMS to complete its review and approval process for state compliance. Depending on policies and structures, states will need to conduct thorough policy analysis and may need state plan amendments, systems

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changes and contract revisions.

An overwhelming number of commenters urged CMS to shorten the timeframe for states to come into compliance with the parity rules. Many referenced the fact that the proposed rule comes more than 5 years after the MHPAEA parity protections were applied to MCOs in 2008. States have been aware since passage of MHPAEA that its requirements apply to Medicaid MCOs and CHIP programs. Additionally states have known that these requirements apply to Medicaid ABPs since the passage of the Affordable Care Act in 2010. Recommendations to CMS from these commenters proposed a range of 6 to 12 months for states to come into compliance with this final regulation.

Several commenters recommended to CMS that health plans and their subcontractors not be penalized as a result of a state Medicaid agency experiencing delays in implementing the final rule in the required timeline. Additionally, it was requested that CMS allow plans an additional six months after a state has completed the parity analysis and developed the necessary standards to come into compliance.

Response: We are finalizing §438.930 with a modification from the proposed text; §438.930, as finalized, states that contracts with MCOs, PIHPs, and PAHPs offering Medicaid state plan services to enrollees, and those entities, must comply with the requirements of this subpart no later than 18 months after the date of publication of this final rule. The proposed rule required such compliance no later than the beginning of the contract year starting 18 months after the date of publication of this final rule. Because a contract year could begin just before the date of publication of this final rule, the proposed rule could potentially have allowed a plan an additional period of up to 12 months beyond expected compliance date (that is, roughly 18 months after the publication date of this final rule) before being subject to any CMS enforcement action. Therefore, this change responds to commenter concerns about delays in implementation

by ensuring that necessary changes are implemented no more than 18 months after the date of publication of this final rule. This change also aligns the compliance date for MCOs, PIHPs, and PAHPs with the compliance dates proposed for ABPs and CHIP, finalized here in §440.395(e)(4) and §457.496(g). We note that it is common practice for states to amend MCO contracts mid-year, so we do not anticipate that it will cause an undue burden to states to make any needed changes to their MCO, PIHP, or PAHP contracts by the stated compliance date.

For ABPs and CHIP, we will finalize the proposed policy to allow 18 months from the publication date of this final rule for states to establish compliance with the provisions of this final rule. While we understand that many commenters believe that states and MCOs should be complying with parity given the statute and subregulatory guidance, we believe that the regulations will require states and plans to make additional changes to their benefits and how they manage these benefits. In addition, the major reasons for allowing states 18 months to establish compliance with these rules are still relevant, including states' ability to get the necessary information to perform the parity analysis across delivery systems. As noted in other sections of the preamble, we may decline to approve MCO contracts and defer FFP if the state cannot establish that the benefits and delivery system are compliant with these rules. States may want to consider including penalties in their contracts if it is found that one of the managed care plans is the reason for the non-compliance.

Comment: Many commenters suggested that CMS include in the final rule language describing the CMS process for review and oversight of state attestations of compliance including benchmarks for states to follow for complying with this final regulation. The commenters recommended that benchmarks include the state's actions to bring coverage into compliance with the final regulation. Recommended actions included having all MCO contracts implemented or renewed prior to the deadline in order to fully comply, ensuring that all FFS

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CHIP and ABP coverage meets parity and that states have taken all steps for compliance except some of the more time consuming steps such as renegotiating MCO contracts or passing authorizing legislation.

Response: We understand the utility of providing states with guidance about the states' role in ensuring that compliance is achieved in a timely manner. We have procured a contractor to provide technical assistance as requested by the states that may include toolkits or guidance regarding the creation of a parity implementation plan.

As indicated in the response to comments, we are finalizing the provisions regarding applicability and compliance at §438.930, §440.395(d), §457.496(f) as proposed, with two exceptions. First, we are finalizing the ABP compliance provision with a different paragraph designation, §440.395(e). Second, we are modifying the MCO compliance provision to align with the timing in final §440.395(e) and §457.496(g), applicable to ABPs and CHIP respectively.

Q. Utilization Control

Current Medicaid regulations concerning utilization control include requirements for the review of need for admission into mental hospitals (§456.171). These regulations specifically require medical and other professionals within the Medicaid agency (or its designee) to evaluate each beneficiary's need for admission into inpatient services in a mental hospital. There is not a similar requirement for the Medicaid agency to review each beneficiary's medical/surgical admission to other hospitals. States have indicated that this regulation presents challenges to achieving parity for inpatient services rendered in a mental hospital. We proposed to eliminate §456.171 (namely, the current regulatory language that requires Medicaid agencies to evaluate each applicant's or beneficiary's need for admission into inpatient services in a mental hospital by reviewing and assessing the hospital's medical, psychiatric and social evaluations). A state could continue these evaluations, but would have to ensure that the standards and processes are

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consistent with the provisions in this regulation regarding nonquantitative treatment limits when parity requirements under this rule are applicable.

Comment: Several commenters supported the elimination of the requirement at §456.171 regarding the Medicaid agency review of the need for admission to a mental hospital. The commenters supported the elimination of required review for inpatient admissions because the requirement would be inconsistent with the proposed rule's provisions that utilization management techniques need to be applied in a comparable and no more restrictive manner with respect to mental health and substance use services as compared to medical/surgical services.

Response: This final rule removes the Medicaid regulation at §456.171 which prescribed requirements for medical and other professionals within the Medicaid agency (or its designee) evaluating the need for admission of each applicant or beneficiary into inpatient services in a mental hospital. The Medicaid agency (or its designee) was required to review and assess the hospital's medical, psychiatric, and social evaluations. There was not a similar requirement for the Medicaid agency to review the hospital's evaluation of each applicant's or beneficiary's need for medical/surgical admissions. As a result, this requirement presented a challenge to achieving parity for inpatient services rendered in a mental hospital.

Comment: Some commenters opposed the elimination of the requirement at §456.171. Specifically, the commenters believed in the importance of this pre-admission evaluation to protect individual rights, which is also required under state law. The commenters recognized that the proposed rule allowed states to continue these evaluations as long as the standards and processes for nonquantitative treatment limitations are also met, but were concerned that this may prove difficult to impossible to do. The commenters were concerned that removing the ability for appropriate evaluation of inpatient admissions could remove a certain level of protection for the individual that the regulation currently provides.

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Another commenter recommended against the elimination of evaluations of medical necessity of inpatient psychiatric hospital admissions proposed within the proposed regulations. The commenter maintained that the elimination of these evaluations could compromise states' and MCOs' ability to ensure that the services provided are necessary and appropriate within the context of the entire spectrum of behavioral health care provided within the state.

Response: This final rule eliminates the requirement at §456.171. Eliminating this requirement will still allow states to evaluate individuals need for admission to inpatient psychiatric facilities. However the factors used in states' reviews of the inpatient hospital evaluations for admission must be comparable to and applied no more stringently than factors used in applying the limitation for medical surgical/benefits in the classification. As stated in this final regulation, factors mean the processes, strategies, evidentiary standards, or other considerations used in determining limitations on coverage of services. The phrase "applied no more stringently" requires that any processes, strategies, evidentiary standards, or other factors that are comparable on their face be applied in the same manner to medical/surgical benefits and MH/SUD benefits.

Comment: One commenter recommended removing the federal preadmission requirement from 42 CFR Part 441 Subpart D, Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs. In addition, this commenter requested CMS use precise language to avoid confusion and misperceptions that Institution for Mental Disease (IMD) exclusion does not apply to children under 21.

Response: To clarify, the final rule does not make changes to the certification of need and other requirements applicable to the Inpatient Psychiatric Services for Individuals under Age 21 benefit described at §440.160 and Subpart D §441.150 through 441.182. The Inpatient

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Psychiatric Services for Individuals under Age 21 benefit remains an exception to the IMD exclusion.

As indicated in the response to comments, we are finalizing the removal of §456.171 as proposed.

R. Institutions for Mental Disease

The IMD exclusion is a statutory prohibition on providing Medicaid matching funds for services provided to individuals aged 21 to 64 who are inpatients in IMDs. IMDs are defined in statute as any hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services. This exclusion has been in place since Medicaid was established in 1965 and was based on amendments to the statute that predated Medicaid and prohibited cash assistance payments for services for individuals in IMDs. The proposed regulation did not address the IMD payment exclusion. We received several comments on the applicability of this regulation on our IMD payment policy. While we understand commenters' concerns, we are not making changes to this rule on this topic for the reasons set forth below.

Comment: Many commenters suggested that CMS revisit IMD policies. The commenters stated that the Medicaid payment exclusion for services in IMDs is a barrier to equitable access to inpatient behavioral health services. The commenters indicated that federal action is needed to remove this obstacle to parity and ensure Medicaid programs can meet the needs of beneficiaries with mental health and substance use disorders across the continuum of care. Several commenters recommended that CMS pursue congressional action to repeal or grant exceptions to the IMD exclusion for psychiatric patients admitted emergently to acute, short-stay psychiatric hospitals regardless of their bed size. A few commenters recommended

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that the final rule should clearly state that the IMD exclusion does not or should not apply to SUD residential or detoxification services or psychiatric patients admitted to crisis stabilization or other short-term residential rehabilitation services regardless of bed size. Another commenter indicated that the IMD exclusion precludes providers from creating specialized, centers of excellence for treating mental health and substance use disorders when 24-hour care is needed.

Response: The text following section 1905(a)(29) of the Act provides that FFP is not available for any medical assistance under title XIX for services provided to an individual ages 21 to 64 who is a patient in an IMD facility. Under this broad exclusion, FFP is generally unavailable for the cost of services (regardless of whether the services address physical or mental health) provided either inside or outside the IMD while the individual is a patient in the facility.

Comment: Several commenters were concerned about the IMD exclusion from a parity standpoint because there is no comparable restriction for medical/surgical benefits, and therefore, the exclusion unnecessarily serves to limit access to services based upon a quantitative restriction. Other commenters requested guidance about how to apply the IMD exclusion alongside this rule's guidance that restrictions based on facility type are a NQTL. Commenters also requested information about how parity protections apply to the full range of MH/SUD services typically provided in facilities that fall under the IMD exclusion.

Response: The payment exclusion for Medicaid services provided to beneficiaries in IMDs is a statutory requirement established by the Congress in 1965 and therefore beyond the scope of this regulation. The full range of covered services, including MH/SUD services, could be provided to beneficiaries when they are in facilities that are not IMDs.

Comment: Several commenters recommended reconciling the IMD exclusion with the parity rules in the ABP context by interpreting the Medicaid statute as not applying the IMD exclusion to ABPs. The commenters maintained that CMS's current position is inconsistent with

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section 1937 of the Act, which provides that ABP coverage is provided notwithstanding ... any other provision of Title XIX that “would be directly contrary to [section 1937].” These commenters also state that section 1937 of the Act requires that ABPs cover EHBs, which must include MH/SUD services based on the benefits in a commercial benchmark plan that is likely to cover some services in psychiatric hospitals or other facilities that would be considered IMDs.

Response: States must offer services under ABPs that reflect the ten EHB categories, including MH/SUD services (42 CFR 440.347). As this final rule states, we did not intend to require states to include specific services within EHB categories offered through an ABP. Nor did we specifically require coverage of any particular inpatient or residential mental health services or treatment settings as part of “inpatient services” provided that the coverage complies with MHPAEA parity requirements. States may, however, be required to provide inpatient or residential mental health services that are included in the section 1937 coverage plan that is the basis for the ABP, or that are included in the base-benchmark plan selected by states to define EHBs for Medicaid. We clarified in the preamble of the final rule 42 CFR 440 published in the **Federal Register** on July 15, 2013 (78 FR 42197) and we clarify for this rule that the IMD payment exclusion applies to all medical assistance, even medical assistance furnished through an ABP. To provide required coverage, a state may thus have to demonstrate that the coverage of inpatient (residential) mental health services is provided in integrated environments that include treatment of both physical and mental health conditions and patients. Finally, we clarify that the requirement that all ABPs comply with MHPAEA parity requirements includes compliance with MHPAEA requirements regarding treatment limits.

Comment: Many commenters requested that CMS clarify how parity could be achieved given the coverage and payment exclusion for services to individuals in IMDs. The commenters requested clarification on access to out-of-network benefits where networks are inadequate.

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Response: To clarify, in a Medicaid managed care environment, if a provider network is unable to provide necessary services covered under the contract to a particular enrollee, the MCO, PIHP, or PAHP must adequately (and on a timely basis) cover these services out-of-network for the enrollee as long as the MCO, PIHP, or PAHP is unable to provide them in-network. Therefore if a beneficiary needs a specific service covered under the contract but the service or provider is not available in the current network, such as inpatient mental health services, the MCO, PIHP, or PAHP will need to cover such services in a non-network hospital that provides inpatient mental health services. However, the IMD payment exclusion would apply regardless of whether the facility that provides inpatient mental health services is in network or out-of-network.

Comment: Several commenters requested guidance about how to align parity requirements with policies that will be finalized regarding IMDs in the Medicaid managed care proposed rule.

Response: Because the proposed rule, Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability (80 FR 31098 through 31297) has not yet been finalized, we are unable to comment on the alignment of those requirements with this final rule at this time. When the Medicaid managed care rule is finalized, CMS will provide guidance and technical assistance as needed to help states understand the interplay between the requirements of these rules.

Comment: A few commenters urged CMS to continue to examine, through the Medicaid Emergency Psychiatric Demonstration project, whether eliminating or restricting the scope of the IMD exclusion can improve access to care and help reduce costs.

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Response: In December 2013, we provided an interim Report to Congress on the Medicaid Emergency Psychiatric Demonstration project,⁹ and we will submit a final report in 2016. This report will provide information on the impact that this demonstration project had on access to care and the cost of these services.

For the reasons indicated in the response to comments, we do not include provisions in the final rule that are specific to IMDs.

S. Medicare-Medicaid Dual Eligible Beneficiaries

We received a number of comments about individuals who are dually eligible for both Medicaid and Medicare and the provision of both Medicaid and Medicare benefits to such beneficiaries. Mental health parity requirements under section 2726 of the PHS Act do not apply to Medicare Parts A, B, or D services covered by Medicaid MCOs, such as those covered by integrated plans for Medicare-Medicaid beneficiaries. The proposed rule noted that Medicare benefits are controlled by the Medicare statute and regulations, which are not within the scope of this rule.

Comment: Several commenters stated that it would be impractical, if not impossible, to isolate Medicare benefits from Medicaid benefits for the purposes of determining which aspects of a Medicare-Medicaid integrated care model must comply with MHPAEA. Other commenters noted that administrative difficulties that could arise under the proposed policy, including the complexity of applying NQTL standards to drugs covered by Medicaid but not covered by Medicare Part D. The commenters raised concerns that situations like this could result in increased fragmentation at a time when CMS has taken steps to better integrate coverage for Medicare-Medicaid beneficiaries. The commenters encouraged CMS to ensure that a beneficiary's entire benefit package of items and services meets parity standards, regardless of

⁹ This interim report can be accessed online at http://innovation.cms.gov/files/reports/mepd_rtc.pdf

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the entity or program that is responsible for financing the care, stating that this approach would ensure equitable access to MH/SUD by beneficiaries across all programs, and would also support issuers and states in meeting compliance standards.

Response: The MHPAEA statute does not apply to Medicare, and we lack the statutory authority to apply this rule to Medicare benefits. In states participating in the CMS Financial Alignment Initiative that are implementing a capitated model in which beneficiaries are enrolled in managed care plans, we will provide technical assistance as needed about how to structure and assess those plans for compliance with MHPAEA.

For the reasons indicated in the response to comments, we do not include provisions in the final rule that are specific to coverage provided to Medicare-Medicaid beneficiaries.

IV. Summary of Changes

For the most part, this rule finalizes the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

- We have revised the definitions in §438.900, §440.395(a) and §457.496(a) so that long term services are included in the definition of medical/surgical benefits, mental health benefits, and substance use disorder benefits and that the provisions of this final regulation apply to these services.
- We are finalizing §438.910(b)(2), §440.395(b)(2)(ii) and §457.496(d)(2)(ii) with a modification that requires the standards used to assign mental health/substance use disorder benefits to a classification be reasonable as well as the same as the standards used for medical/surgical benefits.
- We have revised §438.910(d)(3) and §457.496(d)(5) to eliminate the deeming provision; as finalized these rules do not provide that MCOs or CHIP state plans will be deemed

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in compliance with parity solely based on adherence to §438.206(b)(4); this revision clarifies that the requirements of these two provisions are complementary.

- We have also revised the language in §438.910(d)(3) and §457.496(d)(5), as proposed it included a requirement to use the “same” standards regarding access to out-of-network providers, to more closely align with the general requirement for NQTLs; the rule is finalized to require the use of “comparable” standards.

- We have revised §438.6(n) to require MCO contracts to provide for services to be delivered in compliance with this rule and new subpart K, rather than requiring those contracts to ensure that enrollees actually receive such services.

- We have modified §438.905(a) to change the heading and delete designation of (a)(1).

- We have revised §438.920(b)(1) to clarify that states have to review both medical/surgical benefits and MH/SUD benefits when completing the parity analysis. We have also specified in §438.920(b)(1) that information on compliance with the rule must be made available on a state’s website, that such documentation must be provided within 18 months of the date of publication of this final rule, and that the documentation must be updated with any change in MCO, PIHP, PAHP or Medicaid state plan benefits. Minor revisions have also been made to the wording of this provision.

- We have revised §438.920(b)(2) to require the state to ensure that all services be delivered to the enrollees of the MCO in compliance with this rule, regardless of whether the MCO covers all services or only a portion of the services.

- We have modified §438.930 to provide that contracts with MCOs, PIHPs, and PAHPs offering Medicaid state plan services to enrollees, and those entities, must comply with the requirements of this subpart no later than 18 months after the date of publication of this final rule, regardless whether that date is the start or middle of a contract year.

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- Consistent with the statute, we have added a new provision at §440.395(c) to state that when ABPs are offering EPSDT services, they will be deemed in compliance with parity. We have also redesignated the remaining paragraphs and references accordingly.

- We have modified §440.935(d)(1) to replace “Alternative Benefit Plans” with “ABPs” in the heading.

- We have revised 440.395(e)(2) to reflect that Essential Health Benefits are defined to potentially include more than the minimum 10 EHBs.

- We have modified §457.496 throughout to replace “CHIP state plans” with “state plan.”

- We have added clarifying language to the definition of EPSDT benefits within §457.496(a) to indicate that states must provide services described in section 1905(r) of the Act in manner that is compliant with section 1902(a)(43) of the Act.

- We have modified §457.496(b) to specify the requirements states must follow in order for their separate CHIP to be deemed compliant with the MHPAEA parity requirements. These modifications include not excluding benefits on the basis of condition or diagnosis, and including a description of their efforts to comply with the deeming requirements within the state plan.. We also provide that if a state has elected in its state child health plan to cover EPSDT benefits only for certain children eligible under the state child health plan, the state is deemed compliant with this section only with respect to such children.

- We have modified §457.496(d)(5) to refer to “providers for mental health or substance use disorder benefits” instead of “providers for mental health and substance use disorder benefits.”

- We have modified §457.496(f)(1) to specify that states must describe the standard being used to define medical/surgical, MH, and SUD benefits in their state plan.

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- We have modified § 457.496(f)(1) to replace “State Medicaid agency” with “State.”
- We have added a new § 457.496(f)(1)(i) and (ii) and redesignated the remaining provisions of this section.
- We have revised the regulatory text as applicable throughout to replace the acronym “MH/SUD” with the full phrase “mental health and substance use disorder” or “mental health or substance use disorder”

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our April 10, 2015, proposed rule (80 FR 19418) we solicited public comment on each of the section 3506(c)(2)(A) required issues for the following information collection requirements. PRA-related comments were received as indicated below in section V.D. under “Comments Associated with the Proposed Collection of Information Requirements.” While the changes that were made as a result of these comments did not revise the majority of the proposed requirements and burden estimates, burden for the requirements under §438.920 (specific to

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performing and posting the parity analysis on the state's website) have been added to this final rule based on the comments received. Commenters raised concerns that the cost analysis of the proposed rule fails to consider the administrative cost to the states of providing MH/SUD services through MCOs and through FFS delivery systems. The proposed rule did not set forth such burden since we requested comments on our proposed approach.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2014 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 2 presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

TABLE 2: 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. |

*The wage estimates from the proposed rule have been revised to account for more recent BLS data.

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.

B. Information Collection Requirements (ICRs)

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))

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

In the tri-Department MHPAEA final rule, the regulatory impact analysis (78 FR 68253 through 68266) quantified the costs for health insurance issuers and group health plans 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, PIHPs and PAHPs, ABPs and CHIP, and the population covered.

Labor Costs for Medical Necessity Disclosures. Consistent with our proposed rule, we are unable to estimate with certainty the number of requests for medical necessity criteria disclosures that will be received by regulated entities. While we did not receive any public comments on this point, the MHPAEA final rule's impact analysis set forth assumptions that we believe are relevant for calculating costs for the Medicaid and CHIP program. The impact analysis 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 which was applied to the number of beneficiaries enrolled in Medicaid MCOs (33.1 million), ABP (8.7 million) and CHIP (5.7 million) to project 142,403 expected requests (99,328 for MCOs + 26,100 for ABPs +16,975 for CHIP).

To estimate the time it will take medical staff to respond to each request, we used the assumption in the MHPAEA final rule's impact analysis. Specifically, we assumed that it took a staff member (in this case, a medical secretary) 5 minutes to respond to the request. In this rule, this results in a total annual burden of 11,867 hours (142,403 requests x 5 min/60) at a cost of \$382,592.08 (11,867 hours x \$32.24/hour) for all Medicaid and CHIP programs. The state costs for this burden is \$153,037 (state match is 40 percent of costs).

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. As shown in Table 3, mailing and supply costs are \$58,272 (88,291 responses X \$.66). State share for this cost is \$23,309. Total state share costs are \$176,346 (\$153,037 in labor costs and \$23,309 in mailing costs)

Table 3 also 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).¹⁰ CHIP enrollment is based on Medicaid and CHIP Payment and Access Commission’s 2014 estimates.

TABLE 3: 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. | 266,850.48 | 61,584 | 40,645 | 307,496 | \$122,998 |
| ABP | 8,700,000 | 26,100 | 2,175 hr. | 70,122.00 | 16,182 | 10,680 | 80,802 | \$32,321 |
| CHIP | 5,658,460 | 16,975 | 1,415 hr. | 45,619.60 | 10,525 | 6,947 | 52,567 | \$21,027 |
| TOTAL | 47,467,922 | 142,403 | 11,867 hr. | 382,592.08 | 88,291 | 58,272 | 440,865 | \$176,346 |

Submitting Requests for Medical Necessity Disclosures (Potential Participants, Beneficiaries, and Contracting Providers). Table 4 displays the added burden estimates,

¹⁰ Estimates are based on the most recent data available at the time of the analysis.

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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 4: 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. |

The aforementioned requirements and burden will be submitted to OMB for approval under control number 0938-1280 (CMS-10556).

2. ICRs Regarding the Availability of Information and Reason for Any Denial (§§ 438.915(b), 440.395(c)(2), and 457.496(e)(2))

MHPAEA requires that the reason for any denial -- under a group health plan or health insurance coverage -- of reimbursement or payment for MH/SUD benefits must be made available (upon request or as otherwise required) by the plan administrator (or the health insurance issuer) to the beneficiary in accordance with MHPAEA regulations (45 CFR 146.136(d)(2)).

This final rule only addresses disclosure of information concerning the denial of reimbursement or payment for MH/SUD benefits. We believe that these requirements are already met by complying with existing disclosure requirements in parts 438 and 431, and therefore, do not create any new or revised requirements or burden beyond what is currently

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approved by OMB under control number 0938-1080 (CMS-10307). We also believe that these requirements are already met for CHIP by complying with existing notification and disclosure requirements in §457.110 and §457.1130, and therefore, do not create any requirements or burden beyond what is currently approved by OMB under control number 0938-1148 (CMS-10398 #34) (formerly, CMS-R-211, control number 0938-0707). For ABPs, these provisions do not create any new or revised third-party disclosure requirements beyond what is currently approved by OMB under control number 0938-1188 (CMS-10434).

3. ICRs Regarding Parity in Mental Health and Substance Use Disorder Benefits in Alternative Benefit Plans (§440.395)

When a state plan provides for an ABP, the state must provide sufficient information in an ABP state plan amendment (§440.300) request to assure compliance with the requirements of (§440.395(e)(3)), including the application of parity to treatment limitations as addressed in this rule. The ABP state Plan Application is employed by states to identify benefits offered to Medicaid beneficiaries receiving services under section 1937 of the Act. The application requires that states identify the MH/SUD services that will be offered under the plan. The plan also collects information on any limitations (quantitative and nonquantitative treatment limitations) and financial requirements across all benefit categories (including all medical/surgical services).

The parity requirements in §440.395 do not impose any new or revised reporting, recordkeeping, or third-party disclosure requirements for 10 or more states since only one state and three territories operate their ABP state plan in FFS, and therefore, do not require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These states that operate the ABP programs in a fee-for-service only delivery system would not have to perform an additional parity analysis across the various delivery systems.

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States that operate their ABP programs through a managed care arrangement would be required to attest that they are compliant with parity, and to solicit comments on their ABP state plan (which includes requests for comments on this attestation), but that attestation is in an existing PRA: OMB under control number 0938-1188 (CMS-10434). While states are required to solicit public comment, we maintain that the information collection requirement is exempt from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) since we estimate fewer than ten annual respondents (5 CFR 1320.3(c)). As ABPs are most often used by states to expand Medicaid to the adult population, we project that this would apply to no more than 1 to 2 states per year.

4. ICRs Regarding State Plan Amendments (SPAs)

This rule does not impose any new or revised SPA-specific reporting, recordkeeping, or third-party disclosure requirements and therefore does not require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The rule does not require a state to amend its current non-ABP SPA since states have the option of including additional services necessary to meet parity requirements in the MCO, PIHP or PAHP contracts. The burden for amending such contracts is set out below under §438.6(n).

The currently approved ABP SPA template was designed to capture the MHPAEA final rule classifications and identify if there are specific treatment limitations or financial requirements. The ABP SPA template's information collection requirements and burden are not affected by this rule and are approved by OMB under control number 0938-1188 (CMS-10434).

States are required to review their respective CHIP state plans to determine if they are in compliance with federal law, and states must submit a CHIP SPA to make the necessary changes to the state plan to comply with changes in federal law as described in §457.60(a). Section 502 of the CHIPRA amended section 2103(c) of the Act, which was described in SHO letters #09-

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014 and #13-001. Many states have performed parity analyses based on that guidance and submitted SPAs to come into compliance with MHPAEA.

However, as described in section III. G of this final rule, we plan on developing state plan pages specific to MHPAEA, so all states with a separate CHIP must submit a SPA to update their state plan. We anticipate that up to 42 states will need to submit a SPA, which may add up to 160 hrs. of additional burden on states based on the estimated burden of submitting a SPA (80 hrs.) approved by OMB under control number 0938-1148 (CMS-10398 #34) (formerly CMS-R-211, control number 0938-0707). This additional SPA burden is estimated to cost \$12,313.60 (160hrs x \$76.96/hr.) for a social science analyst to submit a complete SPA package; however, the final costs for the states will be much lower because in CHIP it is important to take into account the Federal government's contribution to the cost of administering CHIP. States receive an enhanced FMAP for administering their CHIP program that now includes a 23 percentage increase beginning in FFY 2016, which was maintained through the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The average enhanced FMAP has increased to 92.7 percent, decreasing the state's share of this additional burden to a nominal cost of \$898.89 ($\$12,313.60 \times 0.073$). When ready, the SPA template along with the associated requirements and burden will be submitted to OMB for approval under control number 0938-1148 (CMS-10398 #34). This is a preliminary estimate that is based on our experience with existing SPA templates.

5. ICRs Regarding State Health Official (SHO) Letters SHO # 09-014 (November 4, 2009) and SHO # 13-001 (January 16, 2013)

The January 2013 SHO letter addressed the application of the MHPAEA requirements in Medicaid and expanded upon the CHIP guidance that was provided in the November 2009 letter regarding section 502 of CHIPRA. Since the letters are discussed in section II.A. of this final

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rule (as background), we wish to clarify that this rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements pertaining to either of the letters. Consequently, the PRA does not apply.

6. ICRs Regarding Contract Requirements (§ 438.6(n))

In §438.6(n), states are now 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 at \$67.38/hour for a business operations specialist to amend each contract with provisions that implement the requirements outlined in part 438, subpart K. Applicable to 36 states (which is the number of states that have an MCO model), and to a total of 602 contracts in those states, in aggregate we estimate 301 hours (602 contracts x 0.5 hours) and \$20,281 (301 hours x \$67.38/hr.). State costs for this burden is \$8,112 (40 percent of costs are state match). The requirements and burden will be submitted to OMB for approval under control number 0938-1280 (CMS-10556).

7. ICRs for State 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

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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 384 hours (36 states x 8 hours) and \$19,405 (288 hours x \$67.38/hr.). State costs for this burden is \$7,762. The requirements and burden will be submitted to OMB for approval under control number 0938-1280 (CMS-10556).

C. Summary of Burden Estimates

TABLE 5: Annual Recordkeeping and Reporting Requirements

| Regulation Section(s) Under Title 42 of the CFR | OMB Control No. | 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) (States and Plans) | 0938-1280 | 602 | 142,403 | 5 min | 11,867 | 32.24 | 382,592 | 58,272 | 440,864 | 176,346 |
| 438.915(a), 440.395(c)(1), and 457.496(e)(1) (Potential participants, beneficiaries and providers) | 0938-1280 | 47,467,922 | 142,403 | 15 min | 35,601 | N/A | N/A | N/A | N/A | |
| 438.6(n) (States) | 0938-1280 | 36 | 602 | 30 min | 301 | 67.38 | 20,281 | 0 | 20,281 | 8,112 |
| 438.920 (States) | 0938-1280 | 36 | 36 | 8 hours | 288 | 67.38 | 19,405 | 0 | 19,405 | 7,762 |
| 457.496 (State Plan Amendments) | 0938-1148 | 42 | 2 | 80 hours | 160 | 76.96 | 12,314 | 0 | 12,314 | 899 |
| TOTAL | -- | 47,468,638 | 285,446 | 88 hrs. 50 min | 48,217 | -- | 434,592 | 58,272 | 492,864 | 193,119 |

*This rule does not set forth any capital/maintenance costs.

D. Comments Associated with the Proposed Collection of Information Requirements

Comment: Two commenters expressed concerns that the cost analysis of the proposed rule fails to consider the administrative cost to the states of providing MH/SUD services through MCOs and through FFS delivery systems. They stated that significant administrative costs

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would be associated with creating new ongoing reporting mechanisms for states and MCOs to provide detailed 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. Commenters also stated that these requirements would require state staff to review the rule, review each contract, develop appropriate language needed in each contract, and process the amended contract through the administrative channels. The actual time needed to address this would be many times greater than the proposed estimate.

Response: We recognize that the administrative burden of implementing this rule will vary across states and MCOs, and intend for the numbers cited above are a national estimate of burden across all impacted entities. We note that efficiencies can be achieved regarding implementation of this rule through the use of standardized processes, and that technical assistance provided to states is intended to help to reduce the administrative burden. However, we do agree with the commenters that there will be an additional burden to states to perform and/or review the parity analysis, document compliance and post it to the state's website. We have included the projections of this additional burden in section V.B.7 of this final rule.

E. Submission of PRA-Related Comments

We submitted a copy of this final rule's information collection and recordkeeping requirements to OMB for review and approval. The requirements are not effective until they have been formally approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS' website at www.cms.hhs.gov/Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If

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you wish to comment, please identify the rule (CMS-2333-F) and submit your comments to the OMB desk officer via one of the following transmissions:

Mail: OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: 202-395-5806 OR

E-mail: OIRA_submission@omb.eop.gov.

ICR-related comments are due [INSERT DATE 30-DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule addresses the applicability of the requirements under the MHPAEA to Medicaid non-managed care benchmark and benchmark-equivalent plans (referred to in this final rule as Medicaid ABPs) as described in section 1937 of the Act, CHIP under title XXI of the Act, and Medicaid MCOs as described in section 1932 of the Act.

In 2013, we released a SHO letter that provided guidance to states regarding the implementation of requirements under MHPAEA to Medicaid benchmark and benchmark-equivalent plans (referred to in this letter as ABPs), CHIP, and Medicaid MCOs.

Final regulations implementing MHPAEA were published in the tri-Department MHPAEA final regulations that do not apply to Medicaid MCOs, ABPs, or CHIP state plans.

We believe that in absence of a regulation specific to the application of the parity requirements under MHPAEA to Medicaid and CHIP, states would not be compelled to implement the necessary changes to these programs, resulting in an inequity between beneficiaries who have MH/SUD conditions in the commercial market (including the state and federal marketplace) and Medicaid and CHIP. Even for states that are attempting to comply with

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parity requirements under MHPAEA, the absence of regulation could lead to inconsistent state-specific policies.

This final rule provides the specificity and clarity needed to effectively implement the policies set forth by MHPAEA and prevent the use of prohibited limits on coverage, including nonquantitative treatment limitations that disproportionately limit coverage of treatment for MH/SUD conditions. The Department's assessment of the expected economic effects of this final rule is discussed in detail below.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) (having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants,

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user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this final rule is "economically significant" as measured by the \$100 million threshold, and hence, also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA, which to the best of our ability presents the costs and benefits of the rulemaking.

Because the application of parity requirements to ABPs; MCOs and PIHPs and PAHPs providing services to MCO enrollees; and the CHIP is likely to have an effect on the economy of \$100 million or more in any given year, this final rule is economically significant within the meaning of section 3(f)(1) of the Executive Order as elaborated below, we believe the benefits of the rule justify the costs.

C. Anticipated Effects

This final rule would benefit approximately 22.3 million Medicaid beneficiaries and 880,000 CHIP beneficiaries in 2016, based on service utilization estimates from 2012 Medicaid and CHIP enrollment. We expect that a significant benefit associated with the application of the parity requirements under MHPAEA and these final regulations will be derived from applying parity requirements to the quantitative treatment limits such as annual or lifetime day or visit limits. Applying parity requirements to visit or stay limits will help ensure that vulnerable populations—those accessing substantial amounts of MH/SUD services—have better access to appropriate care. Among adults aged 18 through 64 with Medicaid coverage, approximately 9.6 percent have a serious mental illness, 30.5 percent have any mental illness, and 11.9 percent have

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a substance use disorder.¹¹ Among CHIP beneficiaries, approximately 8 percent of children experience serious behavioral or emotional difficulties.¹²

Evidence-based treatment for severe and persistent mental illness, and for substance use disorders, often requires prolonged (possibly lifetime) treatment that consists of pharmacotherapy, supportive counseling, and often rehabilitative services. Individuals with severe MH/SUD conditions often quickly exhaust their benefits under Medicaid managed care. In addition, CHIP programs may restrict coverage, such as covering only 40 hours of psychotherapy or 5 days of detoxification per year. These coverage restrictions often result in people forgoing outpatient treatment and a higher likelihood of non-adherence to treatment regimes, which produce poor health and welfare outcomes and create the potential for increased hospitalization costs.^{13,14} For those with substance use disorders, treatment retention is of key importance when assessing outcomes, where those who stayed in treatment longer had more success in decreasing their substance use.^{15,16} In 2011, approximately 8 percent of adults with Medicaid coverage reported at least one occurrence in the past 12 months of feeling the need for MH/SUD treatment or counseling but not receiving it.¹⁷ Between 2007 and 2009, approximately 72 percent of children in Medicaid with a potential mental health need did not receive mental

11 Calculations were based on the Substance Abuse and Mental Health Services Administration (SAMHSA) National Survey of Drug Use and Health.

12 Pastor PN, Reuben CA, Duran CR. Identifying Emotional And Behavioral Problems in Children Aged 4–17 Years: United States, 2001–2007. National Health Statistics Report No. 48. Hyattsville, MD: National Center for Health Statistics; 2012.

13 Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2005. Treatment Improvement Protocol (TIP) Series, No. 43.

14 Trivedi AN, Swaminathan S, Mor V. Insurance parity and the use of outpatient mental health care following a psychiatric hospitalization. *JAMA*. 2008 Dec 24;300(24):2879-85.

15 Simpson D, Joe G W, Rowan-Szal G. Drug abuse treatment retention and process effects on follow-up outcomes. *Drug and Alcohol Dependence*. 1997b;47(3):227–235.

16 Hartel D M, Schoenbaum E E. Methadone treatment protects against HIV infection: Two decades of experience in the Bronx, New York City. *Public Health Reports*. 1998;113(Suppl. 1):107–115.

17 Substance Abuse and Mental Health Services Administration (SAMHSA). Behavioral Health United States 2012. HHS Publication No. (SMA)13-4797. Rockville, MD: SAMHSA; 2013.

health services.¹⁸ The most frequently cited reasons for not seeking MH/SUD treatment are cost and/or a lack of health insurance coverage, low perceived need, stigma, or structural barriers (for example, no transportation, did not know where to go).^{19,20} Removing quantitative limits on treatment may be particularly beneficial for individuals with severe mental illness and substance use disorders who may need to receive more services than the average individual.^{21,22} Improved coverage may also reduce the financial burden on individuals and families, particularly those families of children with mental health service needs.²³ Finally, improving coverage of MH/SUD treatment may also improve employment, productivity, and earnings among those with these conditions.²⁴ Wang, et al, found that implementing a care program for those identified with depression yielded not only enhanced clinical outcomes relative to depression, but also produced positive outcomes relative to decreased sick leave and increased productivity.²⁵ Similarly, the State of Washington implemented a substance abuse treatment program for those receiving Aid to Families with Dependent Children (AFDC), and found that access to treatment increased earnings for those with jobs, as well as increased rates of employment.²⁶

Application of parity requirements may also result in changes to payers' utilization

18 GAO. Children's Mental Health: Concerns Remain about Appropriate Services for Children in Medicaid and Foster Care. December 2012. <http://www.gao.gov/assets/660/650716.pdf>. Accessed June 27, 2014.

19 Affordability Most Frequent Reason for Not Receiving Mental Health Services. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2013. The NSDUH Report Data Spotlight.

20 Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings and Detailed Tables. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2013

21 Zuvekas SH, Banthin JS, Selden TM. How would mental health parity affect the marginal price of care? *Health Serv Res.* 2001 Feb;35(6):1207-27. Review

22 McConnell KJ. The effect of parity on expenditures for individuals with severe mental illness. *Health Serv Res.* 2013 Oct;48(5):1634-52. doi: 10.1111/1475-6773.12058. Epub 2013 Apr 5.

23 Barry CL, Busch SH. Do state parity laws reduce the financial burden on families of children with mental health care needs? *Health Serv Res.* 2007 Jun;42(3 Pt 1):1061-84.

24 Dunigan R, Acevedo A, Campbell K, Garnick DW, Horgan CM, Huber A, Lee MT, Panas L, Ritter GA. Engagement in outpatient substance abuse treatment and employment outcomes. *J Behav Health Serv Res.* 2014 Jan;41(1):20-36. doi:

10.1007/s11414-013-9334-2

25 Wang P, Simon GE, Avorn J, Azocar F, Ludman EJ, McCulloch J, Petukhova MZ, Kessler RC. Telephone screening, outreach and care management for depressed workers and impact on clinical and work productivity outcomes. *JAMA* 2007;298(12):1401-11.

26 Wickizer TM, Campbell K, Krupski A, Stark K. Employment outcomes among AFDC recipients treated for substance abuse in Washington State. *Milbank Q.* 2000;78(4):585-608, iv. PubMed PMID: 11191450.

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management approaches, specifically when requiring preauthorization of mental health services. It was found that even when approval for continued access to mental health services was in essence guaranteed, patients required to obtain prior approval sought out less treatment, perhaps believing they “should not” access further needed treatment.²⁷ Hodgkin, et al, found that removal of utilization management approaches (including preauthorization for the first set of mental health visits) increased use of mental health services.²⁸ Cuffel, et al, note that there are various reasons for why an approach like preauthorization can impact provider behavior relative to mental health service. Providers may believe that the preauthorization process is too laborious and not worth their time; they may fear that those reviewing the request will penalize them for submitting a preauthorization request; they may assume that the set limits on services preclude additional requests for services; providers may believe that the initial limits are in place as an implied recommendation towards shorter treatment cycles; and some may believe requests for preauthorization simply will not be approved at all.²⁹ Liu, et al, found a significant correlation between preauthorization processes and the probability of ending mental health treatment prematurely.³⁰

Application of parity requirements under MHPAEA may also have benefits in terms of reduced medical costs. Mental health and physical health are interrelated, and individuals with poor mental health are likely to have physical health problems as well.^{31,32,33} Increased access to

27 Liu, X., R. Sturm, and B. J. Cuffel. 2000. “The Impact of Prior Authorization on Outpatient Utilization in Managed Behavioral Health Plans.” *Medical Care Research Review* 57: 182–95.

28 Hodgkin D, Merrick EL, Horgan CM, Garnick DW, McLaughlin TJ. "Does Type of Gatekeeping Model Affect Access to Outpatient Specialty Mental Health Services?." *Health Services Research* 42. 1 (2007): 104-123.

29 Cuffel, B., McCulloch, J., Wade, R., Tam, L., Brown-Mitchell, R., & Goldman, W. (2000). Patients' and providers' perceptions of outpatient treatment termination in a managed behavioral health organization. *Psychiatric Services*, 51(4), 469-473.

30 Liu, X., Sturm, R., Cuffel, B. (2000) The impact of prior authorization on outpatient utilization in managed behavioral health plans. *Med Care Res Rev*. Jun;57(2):182-95.

31 Druss BG, Walker ER. Mental disorders and medical comorbidity. *Synth Proj Res Synth Rep*. 2011 Feb;(21):1-26. Review

32 National Institute on Drug Abuse. (December 2012). Medical Consequences of Drug Abuse. Retrieved from

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and utilization of MH/SUD benefits may result in a reduction of medical and surgical costs for individuals with mental health conditions and substance use disorders (so called “medical cost offsets”). For example, after receiving treatment, individuals with substance use disorders may experience fewer hospitalizations and emergency room visits stemming from unintended injuries such as accidents and drug overdose. The evidence that treatment results in medical care offsets is stronger for substance abuse treatment than for mental health treatment. For example, an evaluation on the expansion of substance abuse treatment in Washington State’s Medicaid program found per member per month savings of \$160 to \$385 depending on the welfare cohort.³⁴ Another study done on welfare clients³⁴ in Washington State found that those accessing substance use disorder treatment had on average \$2500 less in medical costs than those who did not access treatment. This estimated savings equaled the cost of SUD treatment for individuals accessing SUD treatment.³⁵ While a similar reduction in medical costs may be expected from mental health treatment, most empirical studies have not found a significant medical cost offset from mental health treatment.^{36,37}

1. Costs

a. Cost Associated with Increased Utilization of MH/SUD Benefits.

A primary objective of Congress in enacting MHPAEA was to eliminate barriers that impeded access to and utilization of MH/SUD benefits. Cost increases and increases in capitated rates may occur as a result of increased access and utilization from the application of parity

<http://www.drugabuse.gov/related-topics/medical-consequences-drug-abuse>

33 Bouchery, E. E., Harwood, H. J., Sacks, J. J., Simon, C. J., & Brewer, R. D. (2011). Economic costs of excessive alcohol consumption in the US, 2006. *American Journal of Preventive Medicine*, 41(5), 516–524.

34 Wickizer, T. M., Mancuso, D., & Huber, A. (2012). Evaluation of an innovative Medicaid health policy initiative to expand substance abuse treatment in Washington State. *Medical Care Research and Review*, 69(5), 540-559.

35 Wickizer, T. M., Krupski, A., Stark, K. D., Mancuso, D., & Campbell, K. (2006). The effect of substance abuse treatment on Medicaid expenditures among general assistance welfare clients in Washington State. *Milbank Quarterly*, 84(3), 555-576.

36 Simon GE, Katzelnick DJ. Depression, use of medical services and cost-offset effects. *J Psychosom Res*. 1997 Apr;42(4):333-44. Review.

37 Sturm R. Economic grand rounds: The myth of medical cost offset. *Psychiatry Serv*. 2001 Jun;52(6):738-40.

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requirements and these regulations, but the evidence suggests that any increases will not be large. The impact of parity requirements will depend on the extent to which MCOs, ABPs, and CHIP plans lack benefits in some classifications or manage these benefits inconsistent with such parity requirements.

In the April 30, 2010 final rule on State Flexibility for Medicaid Benefit Packages (75 FR 23068), the assumptions utilized in modeling the estimated economic impact of the associated provisions took into account the costs of the benefit package for the new adult group served through ABPs. Coverage of these benefits was already accounted for in the April 30, 2010 final rule, and therefore, does not need to be repeated here. Because we approved ABPs only after ensuring compliance with MHPAEA, we project that this regulation will result in no additional costs to ABPs.

(1) Effect of Removing Non-compliant Quantitative Treatment Limitations

A review of Medicaid managed care benefits in all 50 states and the District of Columbia revealed that a subset of states (18 states) had Medicaid managed care plans that imposed quantitative treatment limits on outpatient visits, inpatient stays, and intermediate services (for example, intensive outpatient treatment). As indicated in the preamble, some of these quantitative treatment limits are a result of what is currently in a state's Medicaid plan.

A review of CHIP plans indicated that most are already compliant with MHPAEA. CHIP plans that include Medicaid EPSDT are already required to cover mental health and substance abuse services as needed and they are deemed compliant with MHPAEA parity requirements for financial requirements and treatment limitations. It is not permissible to apply annual or lifetime limits to the EPSDT benefit. CHIP stand-alone programs are also already compliant with MHPAEA because of changes to treatment limitations for both MH/SUD benefits and medical

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and surgical benefits required under the Affordable Care Act.³⁸ Among CHIP plans that are Medicaid expansion plans, we found only one to have an explicit quantitative limit.³⁹

We conducted an analysis to determine how the use of services might increase if quantitative limits on Medicaid MCO and CHIP programs were eliminated. Where quantitative limits exist that are non-compliant with parity requirements, states also have the option to align these limits for MH/SUD and medical/surgical benefits consistent with the provisions of this final rule. However, to estimate the highest possible cost impact that could be expected, we simulated the effect of removing visit and day limits in states with limits for treatment users by anticipating that utilization would increase for beneficiaries who were near or exceeded current limits to equal utilization patterns observed in states without limits for Medicaid managed care beneficiaries. This simulation indicated the maximum impact of removing quantitative day and visit limits on MH/SUD services by Medicaid MCOs to be \$109.0 million nationwide (including federal and state costs) in undiscounted dollars in 2016. Using a similar approach, we estimated the maximum impact of removing quantitative limits on CHIP expenditures to be \$42.1 million in undiscounted dollars in 2016.

However, these estimates are the largest possible cost impacts and the actual impact is likely to be lower. One reason is that some states with quantitative limits may have mechanisms in place for beneficiaries to obtain hospital days or outpatient visits beyond the state's limit if such care is determined to be medically necessary. In practice, we anticipate a potentially lower impact than estimated currently, given that quantitative limits may already be routinely exceeded. We found that in most of the 18 states with visit limits, a number of recipients

38 Sarata AK. Mental health parity and the Patient Protection and Affordable Care Act of 2010. Washington, DC: Congressional Research Service; 2011.

39 McConnell KJ, Gast SH, Ridgely MS, Wallace N, Jacuzzi N, Rieckmann T, McFarland BH, McCarty D. Behavioral health insurance parity: does Oregon's experience presage the national experience with the Mental Health Parity and Addiction Equity Act? *Am J Psychiatry* 2012 Jan;169(1):31-8.

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(ranging from 5 to 20 percent) used services beyond the treatment limit, suggesting that exceptions to the quantitative limits may occur in these states. This does not appear to be the case in all states, because in a few states with visit limits ranging from approximately 24 to 40 visits, only 1 or 2 percent of recipients exceeded the limit.

There are no studies to date on how the application of federal parity requirements affects Medicaid spending. However information from states that have passed state-specific parity legislation (which includes application to Medicaid) provides additional support for the projected impact of these regulations on service utilization and spending. For instance, an evaluation of the Oregon parity law found no significant increases in aggregate behavioral health spending or in the percent of individuals using behavioral health services associated with its implementation.⁴⁰ The evaluators surmised that the flexibility in quantitative limits prior to the parity law may be one reason that the implementation of parity did not lead to large increases in spending. Specifically, they found that prior to the implementation of the state parity law; approximately 5 percent of beneficiaries with any behavioral health visits exceeded the specified limits of that plan.

Vermont's parity law is also very similar to MHPAEA. A study of Vermont's parity law found that the share of spending on mental and substance use disorders increased from 2.30 percent to 2.47 percent of total spending for one health plan.⁴¹

Finally, a recent evaluation of the effect of MHPAEA on the commercial market revealed a modest increase in spending on substance use disorder treatment per enrollee (\$9.99, 95 percent CI: 2.54, 18.21), but no significant change in the percent of individuals using

40 McConnell KJ, Gast SH, Ridgely MS, Wallace N, Jacuzzi N, Rieckmann T, McFarland BH, McCarty D. Behavioral health insurance parity: does Oregon's experience presage the national experience with the Mental Health Parity and Addiction Equity Act? *Am J Psychiatry* 2012 Jan;169(1):31-8.

41 Rosenbach M, Lake T, Young C, et al. Effects of the Vermont Mental Health and Substance Abuse Parity Law. DHHS Pub. No. SMA 03-3822, Rockville, MD: Substance Abuse and Mental Health Services Administration; 2003.

substance use disorder services.⁴²

(2) Effect of Classification of Services Requirements

This final rule requires that if the state provides for MH/SUD services under the state plan, MH/SUD services must be provided to MCO enrollees in every classification in which medical/surgical benefits are provided. After reviewing the MH/SUD services provided under Medicaid managed care plans, we identified only two states providing for MH/SUD services under the state plan in which MH/SUD services were excluded from a classification in which medical/surgical benefits are provided. In both states, the excluded services were substance abuse inpatient services. For the purposes of this analysis, we assumed that substance abuse inpatient services would need to be included to the extent that they were provided in a distinct part or unit of a general hospital or facility with 16 or fewer beds. Using data on current use of Medicaid substance use disorder inpatient services and the cost of those services from Medicaid claims data, we estimated that the additional coverage for these services would have led to an increase of \$11.7 million nationwide in undiscounted dollars in 2012.

Table 6 displays the total costs of removing non-compliant QTLs by service and meeting classification of services requirements in 2012.

TABLE 6: Details of Estimated Costs of Meeting QTL and Classification of Services Requirements in 2012

| Mental Health – Medicaid (\$million/year) | | | | |
|---|-------------------|---------------------|-----------------------|--------------|
| Inpatient | Outpatient | Intermediate | Administrative | Total |
| \$19.8 | \$62.3 | \$0 | \$0.3 | \$82.4 |
| Mental Health – CHIP (\$million/year) | | | | |
| Inpatient | Outpatient | Intermediate | Administrative | Total |
| \$0 | \$30.8 | \$0.4 | \$0.04 | \$31.2 |
| Substance Use Disorder – Medicaid (\$million/year) | | | | |

42 Busch SH, Epstein AJ, Harhay MO, Fiellin DA, Un H, Leader D Jr, Barry CL. The effects of federal parity on substance use disorder treatment. Am J Manag Care. 2014 Jan;20(1):76-82.

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| Inpatient | Outpatient | Intermediate | Administrative | Total |
|--|-------------------|---------------------|-----------------------|--------------|
| \$11.7 | \$0 | \$0 | \$0 | \$11.7 |
| Substance Use Disorder – CHIP (\$million/year) | | | | |
| Inpatient | Outpatient | Intermediate | Administrative | Total |
| \$0 | \$0 | \$0 | \$0 | \$0 |
| Total Costs of Removing Quantitative Limits in 2012 (\$million/year) | | | | \$125.3 |

Note: Administrative costs are listed once for Medicaid and CHIP because the expense is all-inclusive for each program; costs are not broken down by service.

Costs for complying with parity rules for each service category were estimated based on a simulation of additional utilization states may incur as a result of removing quantitative treatment limits.⁴³ For the analysis of intermediate services, we examined limits on partial hospitalization and intensive outpatient care.

These figures are calculated based on 2012 Medicaid and CHIP expenditures, which equate to approximately \$125.3 million in additional costs as a result of parity compliance. Given that total Medicaid and CHIP expenditures in 2012 were \$552.6 billion, the impact of this rule would increase Medicaid and CHIP spending by about 0.02 percent each year. As total Medicaid and CHIP expenditures increase over time, the cost impact of mental health parity is expected to rise proportionally. Accordingly, to determine the anticipated impact of mental health parity in cost in future years, we applied growth in Medicaid and CHIP expenditures from the mid-session review of the President’s FY 2016 budget to this cost.⁴⁴ Due to the complexity and uncertainty of predicting changes to Medicaid enrollment and spending if CHIP authorization expires, our estimate assumes that CHIP will be reauthorized in its present form through FY2020. Costs for 2016 through 2020 are displayed in Table 7.

⁴³ We chose to estimate the cost of removing these limits rather than the cost of aligning these limits with the predominant level of the quantitative limit that applies to substantially all medical/surgical benefits in the classification for simplicity, given the complexity of applying the full analysis to every benefit in every state, and because in most cases, less than two-thirds of the medical/surgical benefits in that classification are subject to a quantitative limit.

⁴⁴ President’s Budget for Fiscal Year 2016, available at <http://www.whitehouse.gov/omb/budget/>

TABLE 7: Estimated Costs of CMS-2333 FY 2016-2020 (in millions)

| | FY 2016 | FY2017 | FY 2018 | FY 2019 | FY 2020 |
|----------------|----------------|---------------|----------------|----------------|----------------|
| Federal | 116.0 | 121.9 | 128.7 | 137.1 | 131.8 |
| State | 50.5 | 53.3 | 56.5 | 59.7 | 76.5 |
| Total | 166.5 | 175.2 | 185.3 | 196.8 | 208.3 |

(3) Effect of Medical Cost Offsets

As described above, the cost of improving access to MH/SUD treatment may be offset by a decline in the expenditures on treatments for medical conditions resulting from substance use disorders. There is strong evidence from Medicaid programs to assume a cost offset resulting from improved access to substance use disorder benefits. In contrast, the evidence for cost offset resulting from improved access to mental health benefits is weaker. We anticipate that, on balance, costs stemming from increased utilization of substance use disorder services resulting from application of parity requirements will be largely offset by the savings from reduced medical costs, yielding very little increase in overall costs from increased utilization of substance use disorder services. However, given the difficulty of quantifying the precise cost impact of this reduced use of medical services that is expected to result from enhanced access to substance use disorder services, we have not included any cost offset in our estimates.

Comment: One commenter believed that proper implementation of parity may save money as more beneficiaries will be able to access appropriate care for their conditions, resulting in fewer emergency department visits and hospitalizations as well as improved physical health.

Response: As noted above, we agree that in many cases, additional spending on MH/SUD services may result in savings from reduced medical/surgical costs.

b. Effect of Aligning NQTLs

Under the MHPAEA final rules, medical management can be applied to MH/SUD

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benefits if the processes, strategies, evidentiary standards, or other factors used in applying medical management are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying medical management to medical and surgical benefits. It is difficult to determine whether, at baseline, Medicaid MCOs, PIHPs, PAHPs, ABPs and CHIP programs are applying medical management more stringently to MH/SUD benefits than to medical and surgical benefits. A state-by-state search of available Medicaid documents indicated that most states that use inpatient utilization management techniques for MH/SUD services, such as prior approval or continuing utilization review for inpatient stays, have similar restrictions for medical and surgical conditions. Surveys of commercial plans have also found that inpatient managed care restrictions, such as pre-admission prior approval, are common for medical and surgical admissions.^{45,46} There may be important distinctions in the processes, strategies, evidentiary standards, or other factors between MH/SUD services and medical and surgical services, but current data do not indicate that this is the case in a way that would lead to a clear cost impact.

Moreover, if some Medicaid plans have stricter management controls for MH/SUD services than for medical services, there is scant evidence at this time as to how utilization management will evolve with the application of parity requirements and whether stricter controls would result in higher costs.⁴⁷ For example, stricter controls may lead to underutilization of sub-acute levels of care for MH/SUD conditions, leading to the worsening of both MH/SUD conditions and medical or surgical conditions that ultimately require more costly acute levels of care. Studies of the effect of utilization review and prior approval on MH/SUD inpatient

45 Baker CA, Diaz IS. Managed care plans and managed care features: data from the EBS to the NCS. *Compensation and Working Conditions* Spring 2011:30-6.

46 Claxton, G., DiJulio, B., Whitmore, H., Pickreign, J., McHugh, M., Finder, B., & Osei-Anto, A. (2009). Job-based health insurance: costs climb at a moderate pace. *Health Aff* 2009;28(6):w1002-12.

47 Hodgkin D. The impact of private utilization management and psychiatric care: a review of the literature. *Journal of Mental Health Administration* 1992;19(2):143-57.

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services have revealed mixed results, with some studies showing that these managed care techniques result in lower costs, quantities of treatment, or both, and other studies finding only weak or no effects, or effects that are short term.^{48,49,50,51} As noted above, the studies of Oregon and Vermont, whose parity laws include similar restrictions on medical management, have not shown increases in costs resulting from application of these laws. There is uncertainty regarding the level of increased costs that will result from application of the parity requirement for NQTLs, but there is evidence that any increases may be small.

2. Transfers Resulting From Increased Access Under Medicaid

Transfer payments are monetary payments from one group to another that do not affect total resources available to society. There is a potential that application of parity requirements under MHPAEA will result in transfers among different government entities. MH/SUD services receive greater funding from public sources, such as Medicaid, federal government block grants, state government general funds, and local government funding, than do medical and surgical services.⁵² Over time, MH/SUD spending has been shifting away from state and local funding, toward federal financing, especially Medicaid.⁵³ The potential increase in the availability of MH/SUD services under Medicaid and CHIP as a result of the MHPAEA parity requirements may result in a reduction in use of, and spending on, services financed by other public sources

48 Dickey B, Azeni H. Impact of managed care on mental health services. *Health Aff* 1992 Fall;11(3):197-204

49 Frank RG, Brookmeyer R. Managed mental health care and patterns of inpatient utilization for treatment of affective disorders. *Soc Psychiatry Psychiatric Epidemiol* 1995 Aug;30(5):220-3.

50 Wickizer TM, Lessler D, Travis KM.. Controlling inpatient psychiatric utilization through managed care. *Am J Psychiatry* 1996;153:339-45.

51 Wickizer TM, Lessler D. Do treatment restrictions imposed by utilization management increase the likelihood of readmission for psychiatric patients? *Med Care* 1998;36(6):844-50.

52 Levit KR, Mark TL, Coffey RM, Frankel S, Santora P, Vandivort-Warren R, Malone K. Federal spending on behavioral health accelerated during recession as individuals lost employer insurance. *Health Aff* 2013 May;32(5):952-62.

53 Levit KR, Mark TL, Coffey RM, Frankel S, Santora P, Vandivort-Warren R, Malone K. Federal spending on behavioral health accelerated during recession as individuals lost employer insurance. *Health Aff* 2013 May;32(5):952-62.

such as state and local governments and federal block grants.⁵⁴ Limited sound evidence exists about the size of this effect on states.

D. Alternatives Considered

We considered several other approaches for providing guidance to states regarding the application of the MHPAEA to Medicaid MCOs, ABPs, and CHIP. As stated in the preamble of this final rule, under our current policies, there is no way to ensure that MCO enrollees receive state plan benefits in a way that fully complies with MHPAEA. This is because section 1932(b)(8) of the Act does not apply to the design of the traditional Medicaid state plan, and state plans thus may be designed in a way that does not comply with MHPAEA requirements. Under current guidance, we have said that if an MCO is simply properly applying state plan benefits, there is no violation of section 1932(b)(8) of the Act even if that benefit design does not conform to MHPAEA, because the MCO did not adopt that benefit design and thus was not at fault in its non-compliance. As explained above, we do not believe that this policy effectuates Congressional intent in enacting section 1932(b)(8) of the Act. Further, we believe that implementation of the statute requires that MCO enrollees receive benefits in a manner that complies with MHPAEA.

We considered requiring that all state plan MH/SUD services be included under MCO contracts as the way to ensure that MCO enrollees receive the full protections of MHPAEA. However, we believe that this final rule allows states the most flexibility when applying mental health parity requirements to their Medicaid services across delivery systems. Given that there are many different delivery system configurations that carve out MH/SUD services, this approach allows states to comport with parity requirements for MCO enrollees without

54 Frank RG, Goldman HH, Hogan M. Medicaid and mental health: be careful what you ask for. Health Aff 2003 Jan-Feb;22(1):101-13.

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completely carving out MH/SUD services from their MCO or dropping MH/SUD coverage altogether.

Also, under current statutes, regulations and policies, states would not be required under federal law to apply MHPAEA provisions to PIHPs and PAHPs (many of which provide MH/SUD services) since these arrangements were not specifically addressed in section 1932(b)(8) of the Act, and MHPAEA does not directly apply to such contracts. Consideration of these unique state MH/SUD delivery systems is an important distinction in Medicaid when compared to the commercial market. Further, because the statutory provisions making mental health parity requirements applicable to MCOs do not explicitly address these situations, additional interpretation is needed.

In addition to the delivery system issues, states would not be required to remove or align limits on services that were in the state plan for individuals enrolled in an MCO. As stated previously in this regulation, these limits are carried through in the development of rates, and cost of services outside of the state plan or a waiver of the state plan cannot be included. Without the change in this rule, individuals enrolled in an MCO could still be subject to treatment limitations that are not compliant with parity requirements, which we believe is inconsistent with the intent of Congress in requiring in section 1932(b)(8) of the Act that MCOs deliver services in a manner consistent with MHPAEA requirements and the policies regarding application of MHPAEA to ABPs and CHIP that operate in a FFS arrangement. In addition, without these changes to the managed care rate setting process, it will be difficult for MCOs to comply with statutory requirements regarding financial requirements and treatment limitations.

Finally, there are mental health parity provisions that are not applicable to the FFS delivery systems for Medicaid ABP benefits; these include annual and lifetime dollar limits, availability of plan information, and access to out-of-network providers.

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In addition, we considered the ability to provide guidance and enforce the provisions of MHPAEA's application to Medicaid and CHIP through sub-regulatory guidance. Over the past 6 years, we have used two SHO letters to provide guidance to states regarding MHPAEA and Medicaid and CHIP. While states and other stakeholders found this guidance useful, there were many questions or concerns regarding the lack of specificity regarding application of MHPAEA parity requirements to Medicaid and CHIP. There were several issues that states raised regarding this sub-regulatory guidance. One issue was the actuarial soundness requirements, which mandate that MCO payments be based on services as covered under state plans. Another was additional clarification of NQTLs and states' concerns regarding existing federal and state policies that required utilization management strategies that were inconsistent with the intent of MHPAEA. States also raised additional questions regarding application of MHPAEA parity requirements to other delivery systems including PIHPs, PAHPs, and FFS. We do not believe that additional subregulatory guidance would provide the necessary authority for MCOs and states to implement or enforce MHPAEA parity requirements for Medicaid beneficiaries enrolled in an MCO.

E. Accounting Statement and Table

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4/), in Table 8 we have prepared an accounting statement showing the classification of the impacts associated with implementation of this final rule.

The projected impact on costs in 2016 was calculated by multiplying the percent anticipated increase in cost due to the application of parity requirements by expected Medicaid expenditures in 2016. Based on our analysis, the parity rule will lead to an increase of approximately 0.03 percent in total Medicaid spending each year over 10 years. In 2016,

Medicaid expenditures overall are projected to equal approximately \$540.3 billion.⁵⁵ Thus, the undiscounted cost of the rule is estimated to be \$178.1 million in 2016, and to rise proportionate to the growth in overall Medicaid spending in future years. These costs are split between the federal and state governments based on the population covered and the statutory matching rate.

TABLE 8: Accounting Statement: Classification of Estimated Benefit, Costs, and Transfers

| Category | Estimates | Units | | |
|---|-----------|-------------|---------------|----------------|
| | | Year Dollar | Discount Rate | Period Covered |
| Transfers from Federal Government to Providers | | | | |
| Annualized Monetized (\$million/year) | 126.5 | 2016 | 7% | 2016 - 2020 |
| | 126.8 | 2016 | 3% | 2016 - 2020 |
| Transfers from State Government to Providers | | | | |
| Annualized Monetized (\$million/year) | 58.5 | 2016 | 7% | 2016 - 2020 |
| | 59.0 | 2016 | 3% | 2016 - 2020 |

Note. The displayed numbers are rounded to the nearest thousand and therefore may not add up to the totals.

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief for small entities, if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.5 million to \$38.5 million in any 1 year). States are not included in the definition of a small entity. This final rule does not change the rates at which providers would be reimbursed

55 Centers for Medicare & Medicaid Services. National Health Expenditure Projections 2012-2022. Forecast Summary. <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf>. Accessed June 25, 2014 .

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for any additional treatments and services that may be required, and MCOs, PIHPs, and PAHPs will be paid on an actuarially sound basis for any additional coverage that they will be required to provide. As indicated previously in this final rule, the increased costs will be borne by states and the federal government, which are not considered small entities. Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities as that term is used in the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. The Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. Currently, that is approximately \$144 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those “Federal mandate” costs resulting from (A) imposing enforceable duties on state, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs. The average state share of total Medicaid spending in 2016 is projected to be 38.2 percent. The total cost impact of this rule is estimated to be \$178.1 million in 2016. Therefore, the total cost to states is projected to be approximately

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\$68.0 million. Therefore, this final rule is not subject to UMRA.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications.

In the Secretary's view, this final rule has Federalism implications, because it has direct effects on the states, the relationship between the federal government and states, or on the distribution of power and responsibilities among various levels of government. However, in the Secretary's view, the Federalism implications of this final rule are substantially mitigated because, with regards to MCOs, ABPs, and CHIP, the Secretary expects that many states already offer benefits under their state plan and MCO contracts that meet or exceed the Federal mental health parity standards that would be implemented in this rule.

Throughout the process of developing these regulations, to the extent feasible within the relevant provisions of the Act, PHS Act and MHPAEA, the Secretary has attempted to balance the latitude for states to structure their state plan services and MCO contracts according to the needs and preferences of the state, and the Congress' intent to provide uniform minimum protections to Medicaid and CHIP beneficiaries in every state. By doing so, it is the Secretary's view that this final rule complies with the requirements of Executive Order 13132.

I. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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List of Subjects

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid reporting.

42 CFR Part 456

Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

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For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 438—MANAGED CARE

1. The authority citation for part 438 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 438.6 is amended by revising paragraph (e) and adding paragraph (n) to read as follows:

§438.6 Contract requirements.

* * * * *

(e) Additional services that may be covered by a MCO, PIHP, or PAHP. A MCO, PIHP, or PAHP may cover, for enrollees, services that are in addition to those covered under the state plan as follows:

(1) Any services necessary for compliance by the MCO, PIHP, or PAHP with the requirements of subpart K of this part and only to the extent such services are necessary for the MCO, PIHP, or PAHP to comply with §438.910; and

(2) Any services that the MCO, PIHP, or PAHP voluntarily agrees to provide.

(3) Only the costs associated with services in paragraph (e)(1) of this section may be included when determining the payment rates under paragraph (c) of this section.

* * * * *

(n) Parity in mental health and substance use disorder benefits. (1) All MCO contracts, and any PIHP and PAHP contracts providing services to MCO enrollees, must provide for services to be delivered in compliance with the requirements of subpart K of this part insofar as those requirements are applicable.

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(2) Any State providing any services to MCO enrollees using a delivery system other than the MCO delivery system must provide documentation of how the requirements of subpart K of this part are met with the submission of the MCO contract for review and approval under paragraph (a) of this section.

3. Subpart K is added to part 438 to read as follows:

Subpart K—Parity in Mental Health and Substance Use Disorder Benefits

Sec.

| | |
|---------|---|
| 438.900 | Meaning of terms. |
| 438.905 | Parity requirements for aggregate lifetime and annual dollar limits. |
| 438.910 | Parity requirements for financial requirements and treatment limitations. |
| 438.915 | Availability of information. |
| 438.920 | Applicability. |
| 438.930 | Compliance dates. |

Subpart K - Parity in Mental Health and Substance Use Disorder Benefits

§438.900 Meaning of terms.

For purposes of this subpart, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a MCO, PIHP, or PAHP.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a MCO, PIHP, or PAHP.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

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Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits are benefits defined in section 1905(r) of the Act.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for items or services for medical conditions or surgical procedures, as defined by the State and in accordance with applicable Federal and State law, but do not include mental health or substance use disorder benefits. Any condition defined by the State as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines). Medical/surgical benefits include long term care services.

Mental health benefits means benefits for items or services for mental health conditions, as defined by the State and in accordance with applicable Federal and State law. Any condition defined by the State as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines). Mental health benefits include long term care services.

Substance use disorder benefits means benefits for items or services for substance use disorders, as defined by the State and in accordance with applicable Federal and State law. Any disorder defined by the State as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines). Substance use disorder benefits include long term care services.

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Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See §438.910(d)(2) for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

§438.905 Parity requirements for aggregate lifetime and annual dollar limits.

(a) General parity requirement. Each MCO, PIHP, and PAHP providing services to MCO enrollees must comply with paragraphs (b), (c), or (e) of this section for all enrollees of a MCO in States that cover both medical/surgical benefits and mental health or substance use disorder benefits under the State plan. This section details the application of the parity requirements for aggregate lifetime and annual dollar limits.

(b) MCOs, PIHPs, or PAHPs with no limit or limits on less than one-third of all medical/surgical benefits. If a MCO, PIHP, or PAHP does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits provided to enrollees through a contract with the State, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(c) MCOs, PIHPs, or PAHPs with a limit on at least two-thirds of all medical/surgical benefits. If a MCO, PIHP, or PAHP includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits provided to enrollees through a contract with the State, it must either—

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(1) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(2) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is more restrictive than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits.

(d) Determining one-third and two-thirds of all medical/surgical benefits. For purposes of this section, the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the total dollar amount of all combinations of MCO, PIHP, and PAHP payments for medical/surgical benefits expected to be paid under the MCO, PIHP, or PAHP for a contract year (or for the portion of a contract year after a change in benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the MCOs, PIHPs, and PAHPs will constitute one-third or two-thirds of the dollar amount of all payments for medical/surgical benefits.

(e) MCO, PIHP, or PAHP not described in this section—(1) In general. A MCO, PIHP, or PAHP that is not described in paragraph (b) or (c) of this section for aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(i) Impose no aggregate lifetime or annual dollar limit, on mental health or substance use disorder benefits; or

(ii) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no more restrictive than an average limit calculated for medical/surgical

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benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery mechanisms, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (e)(1)(ii). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the contract are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a MCO, PIHP, or PAHP may reasonably be expected to incur for such benefits, taking into account any other applicable restrictions.

(2) Weighting. For purposes of this paragraph (e), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (d) of this section for determining one-third or two-thirds of all medical/surgical benefits.

§438.910 Parity requirements for financial requirements and treatment limitations.

(a) Clarification of terms—(1) Classification of benefits. When reference is made in this section to a classification of benefits, the term “classification” means a classification as described in paragraph (b)(2) of this section.

(2) Type of financial requirement or treatment limitation. When reference is made in this section to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (d)(2) of this section for an illustrative list of nonquantitative treatment limitations.

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(3) Level of a type of financial requirement or treatment limitation. When reference is made in this section to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation.

(b) General parity requirement—(1) General rule and scope. Each MCO, PIHP and PAHP providing services to MCO enrollees in a State that covers both medical/surgical benefits and mental health or substance use disorder benefits under the State plan, must not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification furnished to enrollees (whether or not the benefits are furnished by the same MCO, PIHP, or PAHP). Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (b) to financial requirements and quantitative treatment limitations is addressed in paragraph (c) of this section; the application of the rules of this paragraph (b) to nonquantitative treatment limitations is addressed in paragraph (d) of this section.

(2) Classifications of benefits used for applying rules. If an MCO enrollee is provided mental health or substance use disorder benefits in any classification of benefits described in this paragraph (b)(2), mental health or substance use disorder benefits must be provided to the enrollee in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a MCO, PIHP, or PAHP must apply the same reasonable standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a MCO, PIHP, or PAHP provides benefits in a classification

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and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this section apply separately for that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this section:

(i) Inpatient. Benefits furnished on an inpatient basis.

(ii) Outpatient. Benefits furnished on an outpatient basis. See special rules for office visits in paragraph (c)(2) of this section.

(iii) Emergency care. Benefits for emergency care.

(iv) Prescription drugs. Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (c)(2) of this section.

(c) Financial requirements and quantitative treatment limitations – (1) Determining “substantially all” and “predominant” – (i) Substantially all. For purposes of this section, a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(ii) Predominant. (A) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (c)(1)(i) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical

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benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(B) If, for a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the MCO, PIHP, or PAHP may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a MCO, PIHP, or PAHP may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(iii) Portion based on MCO, PIHP or PAHP payments. For purposes of this section, the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the total dollar amount of all combinations of MCO, PIHP, and PAHP payments for medical/surgical benefits in the classification expected to be paid under the MCOs, PIHPs, and PAHPs for a contract year (or for the portion of a contract year after a change in benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(iv) Clarifications for certain threshold requirements. For any deductible, the dollar amount of MCO, PIHP, or PAHP payments includes all payments for claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar

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amount of MCO, PIHP, or PAHP payments includes all payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of MCO, PIHP, or PAHP payment changes.

(v) Determining the dollar amount of MCO, PIHP, or PAHP payments. Subject to paragraph (c)(1)(iv) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a MCO, PIHP, or PAHP for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(2) Special rules -- (i) Multi-tiered prescription drug benefits. If a MCO, PIHP, or PAHP applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (d)(1) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed for medical/surgical benefits or for mental health or substance use disorder benefits, the MCO, PIHP, or PAHP satisfies the parity requirements of this section for prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up/delivery.

(ii) Sub-classifications permitted for office visits, separate from other outpatient services. For purposes of applying the financial requirement and treatment limitation rules of this section, a MCO, PIHP, or PAHP may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (c)(2)(ii). After the sub-classifications are established, the MCO, PIHP or PAHP may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification

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that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(1) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (c)(2)(ii) are:

(A) Office visits (such as physician visits); and

(B) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(3) No separate cumulative financial requirements. A MCO, PIHP, or PAHP may not apply any cumulative financial requirement for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(4) Compliance with other cost-sharing rules. Each MCO, PIHP, and PAHP must meet the cost-sharing requirements in §438.108 when applying Medicaid cost-sharing.

(d) Nonquantitative treatment limitations – (1) General rule. A MCO, PIHP, or PAHP may not impose a nonquantitative treatment limitation for mental health or substance use disorder benefits in any classification unless, under the policies and procedures of the MCO, PIHP, or PAHP as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the classification.

(2) Illustrative list of nonquantitative treatment limitations. Nonquantitative treatment limitations include –

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(i) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(ii) Formulary design for prescription drugs;

(iii) For MCOs, PIHPs, or PAHPs with multiple network tiers (such as preferred providers and participating providers), network tier design;

(iv) Standards for provider admission to participate in a network, including reimbursement rates;

(v) MCO, PIHP, or PAHP methods for determining usual, customary, and reasonable charges;

(vi) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(vii) Exclusions based on failure to complete a course of treatment;

(viii) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the MCO, PIHP, or PAHP; and

(ix) Standards for providing access to out-of-network providers.

(3) Application to out-of-network providers. Any MCO, PIHP or PAHP providing access to out-of-network providers for medical/surgical benefits within a classification, must use processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for mental health or substance use disorder benefits that are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for medical/surgical benefits.

§438.915 Availability of information.

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(a) Criteria for medical necessity determinations. The criteria for medical necessity determinations, made by a MCO or by a PIHP or PAHP providing services to an MCO enrollee, for mental health or substance use disorder benefits must be made available by the MCO, PIHP, or PAHP administrator to any enrollee, potential enrollee, or contracting provider upon request. MCOs, PIHPs, and PAHPs operating in compliance with §438.236(c) will be deemed compliant with the requirements in this paragraph (a).

(b) Reason for any denial. The reason for any denial by a MCO, PIHP, or PAHP of reimbursement or payment for services for mental health or substance use disorder benefits in the case of any enrollee must be made available by the MCO, PIHP, or PAHP administrator to the enrollee.

(c) Provisions of other law. Compliance with the disclosure requirements in paragraphs (a) and (b) of this section is not determinative of compliance with any other provision of applicable Federal or State law.

§438.920 Applicability.

(a) MCOs, PIHPs, and PAHPs. The requirements of this subpart apply to each MCO, PIHP, and PAHP offering services to enrollees of a MCO, in States covering medical/surgical and mental health or substance use disorder services under the State plan. These requirements regarding coverage for services that must be provided to enrollees of an MCO apply regardless of the delivery system of the medical/surgical, mental health, or substance use disorder services under the State plan.

(b) State responsibilities. (1) In any instance where the full scope of medical/surgical and mental health and substance use disorder services are not provided through the MCO, the State must review the mental health and substance use disorder and medical/surgical benefits provided through the MCO, PIHP, PAHP, and fee-for service (FFS) coverage to ensure the full scope of

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services available to all enrollees of the MCO complies with the requirements in this subpart.

The State must provide documentation of compliance with requirements in this subpart to the general public and post this information on the State Medicaid website by October 2, 2017. Such documentation must be updated prior to any change in MCO, PIHP, PAHP or FFS State plan benefits.

(2) The State must ensure that all services are delivered to the enrollees of the MCO in compliance with this subpart.

(c) Scope. This subpart does not –

(1) Require a MCO, PIHP, or PAHP to provide any mental health benefits or substance use disorder benefits beyond what is specified in its contract, and the provision of benefits by a MCO, PIHP, or PAHP for one or more mental health conditions or substance use disorders does not require the MCO, PIHP or PAHP to provide benefits for any other mental health condition or substance use disorder;

(2) Require a MCO, PIHP, or PAHP that provides coverage for mental health or substance use disorder benefits only to the extent required under 1905(a)(4)(D) of the Act to provide additional mental health or substance use disorder benefits in any classification in accordance with this section; or

(3) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the Medicaid MCO, PIHP, or PAHP contract except as specifically provided in §§438.905 and 438.910.

§438.930 Compliance dates.

In general, contracts with MCOs, PIHPs, and PAHPs offering Medicaid State plan services to enrollees, and those entities, must comply with the requirements of this subpart no later than October 2, 2017.

PART 440—SERVICES: GENERAL PROVISIONS

4. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

5. Section 440.395 is added to read as follows:

§440.395 Parity in mental health and substance use disorder benefits.

(a) Meaning of terms. For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under an ABP.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under an ABP.

Alternative Benefit Plans (ABPs) mean benefit packages in one or more of the benchmark coverage packages described in §§440.330(a) through (c) and 440.335. Benefits may be delivered through managed care and non-managed care delivery systems. Consistent with the requirements of §440.385, States must comply with the managed care provisions at section 1932 of the Act and part 438 of this chapter, if benchmark and benchmark-equivalent benefits are provided through a managed care entity.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

EPSDT means benefits defined in section 1905(r) of the Act.

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Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for items or services for medical conditions or surgical procedures, as defined by the State under the terms of the ABP and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. Any condition defined by the state as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines). Medical/surgical benefits include long term services.

Mental health benefits means benefits for items or services for mental health conditions, as defined by the State under the terms of the ABP and in accordance with applicable Federal and State law. Any condition defined by the State as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines). Mental health benefits include long term care services.

Substance use disorder benefits means benefits for items or services for substance use disorder, as defined by the State under the terms of the ABP and in accordance with applicable Federal and State law. Any disorder defined by the State as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines). Substance use disorder benefits include long term care services.

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Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under an ABP. (See paragraph (b)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

(b) Parity requirements for financial requirements and treatment limitations--(1)

Clarification of terms--(i) Classification of benefits. When reference is made in this paragraph (b) to a classification of benefits, the term “classification” means a classification as described in paragraph (b)(2)(ii) of this section.

(ii) Type of financial requirement or treatment limitation. When reference is made in this paragraph (b) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (b)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) Level of a type of financial requirement or treatment limitation. When reference is made in this paragraph (b) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation.

(2) General parity requirement--(i) General rule. A State may not apply within an ABP any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement

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or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (b)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (b)(3) of this section; the application of the rules of this paragraph (b)(2) to nonquantitative treatment limitations is addressed in paragraph (b)(4) of this section.

(ii) Classifications of benefits used for applying rules. ABPs must include mental health or substance use disorder benefits in every classification of benefits described in this paragraph (b)(2)(ii) in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, the State must apply the same reasonable standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a State provides ABP benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (b) apply separately for that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this paragraph (b):

(A) Inpatient. Benefits furnished on an inpatient basis.

(B) Outpatient. Benefits furnished on an outpatient basis. See special rules for office visits in paragraph (b)(3)(ii)(B)(1) of this section.

(C) Emergency care. Benefits for emergency care.

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(D) Prescription drugs. Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (b)(3)(ii) of this section.

(3) Financial requirements and quantitative treatment limitations--(i) Determining “substantially all” and “predominant”--(A) Substantially all. For purposes of this paragraph (b), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) Predominant--(1) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (b)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(2) If, for a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the State may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the

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classification. (For this purpose, a State may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) Portion based on ABP payments. For purposes of this paragraph (b), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all ABP payments for medical/surgical benefits in the classification expected to be paid under the ABP for the plan year (or for the portion of the plan year after a change in ABP benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) Clarifications for certain threshold requirements. For any deductible, the dollar amount of ABP payments includes all payments for claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of ABP payments includes all payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of payment changes.

(E) Determining the dollar amount of ABP payments. Subject to paragraph (b)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) Special rules--(A) Multi-tiered prescription drug benefits. If a State or plan administrator applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in

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paragraph (b)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed for medical/surgical benefits or for mental health or substance use disorder benefits, the ABP satisfies the parity requirements of this paragraph (b) for prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up/delivery.

(B) Sub-classifications permitted for office visits, separate from other outpatient services.

For purposes of applying the financial requirement and treatment limitation rules of this paragraph (b), a State may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (b)(3)(ii)(B). After the sub-classifications are established, the State may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (b)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (b)(3)(ii)(B) are:

(1) Office visits (such as physician visits); and

(2) All other outpatient items and services (such as outpatient surgery, laboratory services, or other medical items).

(iii) No separate cumulative financial requirements. A State may not apply any cumulative financial requirement for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(iv) Compliance with other cost-sharing rules. States must meet the requirements of

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§§447.50 through 447.57 of this chapter when applying Medicaid cost-sharing.

(4) Nonquantitative treatment limitations--(i) General rule. A State may not impose a nonquantitative treatment limitation for mental health or substance use disorder benefits in any classification unless, under the terms of the ABP as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the classification.

(ii) Illustrative list of nonquantitative treatment limitations. Nonquantitative treatment limitations include –

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) Standards for provider admission to participate in a network, including reimbursement rates;

(D) Methods for determining usual, customary, and reasonable charges;

(E) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(F) Exclusions based on failure to complete a course of treatment; and

(G) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits or services provided under the ABP.

(c) ABP providing EPSDT benefits. An ABP that provides EPSDT benefits is deemed to be compliant with the parity requirements for financial requirements and treatment limitations

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with respect to individuals entitled to such benefits. Annual or lifetime limits are not permissible in EPSDT benefits.

(d) Availability of information--(1) Criteria for medical necessity determinations. The criteria for medical necessity determinations made by the State for beneficiaries served through the ABP for mental health or substance use disorder benefits must be made available by the State to any beneficiary or Medicaid provider upon request.

(2) Reason for any denial. The reason for any denial made by the State in the case of a beneficiary served through an ABP of reimbursement or payment for services for mental health or substance use disorder benefits must be made available by the State to the beneficiary.

(3) Provisions of other law. Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law.

(e) Applicability--(1) ABPs. The requirements of this section apply to States providing benefits through ABPs. For those States providing ABPs through an MCO, PIHP, or PAHP, the rules of 42 CFR part 438, subpart K also apply, and approved contracts will be viewed as evidence of compliance with the requirements of this section.

(2) Scope. This section does not –

(i) Require a State to provide any specific mental health benefits or substance use disorder benefits; however, in providing coverage through an ABP, the State must include EHBs, including the ten EHBs as required in §440.347, which include mental health and substance use disorder benefits; or

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the ABP except as specifically provided in paragraph (b) of this section.

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(3) State plan requirement. If a State plan provides for an ABP, the State must provide sufficient information in ABP State plan amendment requests to assure compliance with the requirements of this subpart.

(4) Compliance dates—(i) In general. ABP coverage offered by States must comply with the requirements of this section no later than October 2, 2017.

(ii) [Reserved]

PART 456 -- UTILIZATION CONTROL

6. The authority citation for part 456 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

§456.171 [Removed and Reserved]

7. Section 456.171 is removed and reserved.

PART 457--ALLOTMENTS AND GRANTS TO STATES

8. The authority citation for part 457 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

9. Section 457.496 is added to subpart D to read as follows:

§457.496 Parity in mental health and substance use disorder benefits.

(a) Meaning of terms. For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a State plan or a Managed Care Entity (MCE) (as defined at §457.10) that contracts with the State plan. State plans must meet the requirements of §457.480.

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Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a State plan or a MCE that contracts with a State plan. State plans must meet the requirements at §457.480.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits has the meaning defined in section 1905(r) of the Act and must be provided in accordance with section 1902(a)(43) of the Act.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for items or services for medical conditions or surgical procedures, as defined under the terms of the State plan in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. Any condition defined by the State plan as being or not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or generally applicable State guidelines). Medical/surgical benefits include long term care services.

Mental health benefits means benefits for items or services that treat or otherwise address mental health conditions, as defined under the terms of the State plan in accordance with applicable Federal and State law, and consistent with generally recognized independent standards

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of current medical practice. Standards of current medical practice can be based on the most current version of the DSM, the most current version of the ICD, or generally applicable State guidelines. The term includes long term care services.

State Plan has the meaning assigned at §457.10 and §457.50.

Substance use disorder benefits means benefits for items or services for substance use disorder, as defined under the terms of the State plan in accordance with applicable Federal and State law, and consistent with generally recognized independent standards of current medical practice. Standards of current medical practice can be based on the most current version of the DSM, the most current version of the ICD, or generally applicable State guidelines. The term includes long term care services.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under the State plan. (See paragraph (d)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

(b) State plan providing EPSDT benefits. (1) A State child health plan is deemed to be in compliance with this section if –

(i) The State elects in the State child health plan to cover Secretary-approved coverage defined in §457.450(a) that includes all EPSDT benefits, as defined in section 1905(r) of the Act, in accordance with the requirement applied under section 1905(r)(5) of the Act to provide necessary health care, diagnostic services, treatment, and other measures described in section

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1905(a) of the Act to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, as well as the informing and administrative requirements under 1902(a)(43) of the Act and the approved State Medicaid plan; and

(ii) The State child health plan does not exclude EPSDT benefits for any particular condition, disorder, or diagnosis.

(2) The child health plan must include a description of how the State will comply with paragraph (b)(1)(i) of this section.

(3) If a State has elected in its state plan to cover EPSDT benefits only for certain populations enrolled in the state child health plan, the State is deemed compliant with this section only with respect to such children.

(c) Parity requirements for aggregate lifetime and annual dollar limits. This paragraph (c) details the application of the parity requirements for aggregate lifetime and annual dollar limits. A State plan that provides both medical/surgical benefits and mental health or substance use disorder benefits must comply with paragraph (c)(1), (2), or (4) of this section.

(1) Plan with no limit or limits on less than one-third of all medical/surgical benefits. If a State plan does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(2) State plans with a limit on at least two-thirds of all medical/surgical benefits. If a State plan includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either—

(i) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder

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benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(ii) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is more restrictive than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (d)(3)(iii) of this section prohibiting separately accumulating cumulative financial requirements.)

(3) Determining one-third and two-thirds of all medical/surgical benefits. For purposes of this paragraph (c), the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the State plan for the State plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the State plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

(4) Plan not described in this section--(i) In general. A State plan that is not described in paragraph (c)(1) or (2) of this section for aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(A) Impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no more restrictive than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the

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weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (c)(4)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur for such benefits, taking into account any other applicable restrictions under the plan.

(ii) Weighting. For purposes of this paragraph (c)(4), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (c)(3) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(d) Parity requirements for financial requirements and treatment limitations--(1)

Clarification of terms--(i) Classification of benefits. When reference is made in this paragraph (d) to a classification of benefits, the term “classification” means a classification as described in paragraph (d)(2)(ii) of this section.

(ii) Type of financial requirement or treatment limitation. When reference is made in this paragraph (d) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (d)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

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(iii) Level of a type of financial requirement or treatment limitation. When reference is made in this paragraph (d) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation.

(2) General parity requirement--(i) General rule. A State plan or a MCE that contracts with CHIP through its State plan that provides both medical/surgical benefits and mental health or substance use disorder benefits, including when such benefits are delivered through an MCE, may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (d)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (d)(3) of this section; the application of the rules of this paragraph (d)(2) to nonquantitative treatment limitations is addressed in paragraph (d)(4) of this section.

(ii) Classifications of benefits used for applying rules. If a State plan provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (d)(2)(ii), mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, the same reasonable standards must apply to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a State plan provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment

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limitation) for benefits in the classification, the rules of this paragraph (d) apply separately for that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this paragraph (d):

(A) Inpatient. Benefits furnished on an inpatient basis.

(B) Outpatient. Benefits furnished on an outpatient basis. See special rules for office visits in paragraph (d)(3)(iii) of this section.

(C) Emergency care. Benefits for emergency care.

(D) Prescription drugs. Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (d)(3)(iii) of this section.

(3) Financial requirements and quantitative treatment limitations--(i) Determining “substantially all” and “predominant”--(A) Substantially all. For purposes of this paragraph (d), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) Predominant. (1) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (d)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical

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benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(2) If, for a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the State plan (or health insurance issuer) may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a State plan may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) Portion based on plan payments. For purposes of this paragraph (d), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all State plan payments and combinations of MCE payments for medical/surgical benefits in the classification expected to be paid under the plan or MCE or combination that contracts with the State plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) Clarifications for certain threshold requirements. For any deductible, the dollar amount of a State plan payments includes all plan payments for claims that would be subject to the deductible if it had not been satisfied. In accordance with the cumulative cost-sharing

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maximum in §457.560, or any other out-of-pocket maximum in the State plan, the dollar amount of plan payments includes all State plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of health plan payment changes.

(E) Determining the dollar amount of State plan payments. Subject to paragraph (d)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a State plan for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) Special rules--(A) Multi-tiered prescription drug benefits. If a State plan applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (d)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed for medical/surgical benefits or for mental health or substance use disorder benefits, the health plan satisfies the parity requirements of this paragraph (d) for prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up/delivery.

(B) Sub-classifications permitted for office visits, separate from other outpatient services. For purposes of applying the financial requirement and treatment limitation rules of this paragraph (d), a State plan may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (d)(3)(ii)(B). After the sub-classifications are established, the State plan may not impose any financial requirement or quantitative treatment

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limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (d)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (d)(3)(ii)(B) are:

(1) Office visits (such as physician visits); and

(2) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(iii) No separate cumulative financial requirements. A State plan may not apply any cumulative financial requirement for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(4) Nonquantitative treatment limitations--(i) General rule. A State plan may not impose a nonquantitative treatment limitation for mental health or substance use disorder benefits in any classification unless, under the terms of the CHIP State plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the classification.

(ii) Illustrative list of nonquantitative treatment limitations. Nonquantitative treatment limitations include –

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(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards for provider admission to participate in a network, including reimbursement rates;

(E) Plan methods for determining usual, customary, and reasonable charges;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment;

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage; and

(I) Standards for providing access to out-of-network providers

(5) Application to out-of-network providers. Any State plan providing access to out-of-network providers for medical/surgical benefits within a classification must use processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for mental health or substance use disorder benefits that are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for medical/surgical benefits.

(e) Availability of plan information--(1) Criteria for medical necessity determinations.

The criteria for medical necessity determinations made under a State plan including when

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benefits are furnished through a MCE contractor for mental health or substance use disorder benefits must be made available by the plan administrator (or the State offering the coverage) to any current enrollee or potential enrollee or contracting provider upon request. Health plans operating in compliance with §438.236(c) of this chapter will be deemed compliant with the requirements in this paragraph (e).

(2) Reason for any denial. The reason for any denial under a health plan of reimbursement or payment for services for mental health or substance use disorder benefits in the case of any enrollee must be made available by the plan administrator or the State to the enrollee.

(3) Provisions of other law. Compliance with the disclosure requirements in paragraphs (e)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law.

(f) Applicability--(1) State plans. The requirements of this section apply to State plans offering medical/surgical benefits and mental health or substance use disorder benefits to their enrollees including when benefits are furnished under a contract with MCEs. If, under an arrangement or arrangements to provide State plan benefits any enrollee can simultaneously receive coverage for medical/surgical benefits and coverage for mental health or substance use disorder benefits, then the requirements of this section apply separately for each combination of medical/surgical benefits and of mental health or substance use disorder benefits that any enrollee can simultaneously receive from the State.

(i) Standard for defining benefits. States must indicate the standard used for defining the following benefits in the State plan:

(A) Medical/surgical benefits.

(B) Mental health benefits.

(C) Substance use disorder benefits.

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(ii) [Reserved]

(2) Scope. This section does not –

(i) Require a State plan or a MCE that contracts with a State plan to provide any mental health benefits or substance use disorder benefits, and the provision of benefits by a State plan or a MCE that contracts with a State plan for one or more mental health conditions or substance use disorders does not require the plan or health insurance coverage under this section to provide benefits for any other mental health condition or substance use disorder;

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the State plan or a MCE that contracts with a CHIP State plan except as specifically provided in paragraphs (c) and (d) of this section.

(g) Compliance dates—(1) In general. State plans (including those that contract with a MCE) must comply with the requirements of this section no later than October 2, 2017.

(2) [Reserved].

Dated: February 4, 2016.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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Dated: February 22, 2016.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

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