Top Legal Issues to Expect in 2020

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Overview

Top legal issues to expect in the upcoming year:
- Medicaid Managed Care
- Institutions for Mental Disease (IMD)
- Mental Health Parity/Addiction Equity
- Privacy and Confidentiality
Medicaid Managed Care

Integrated Health
- Illinois to re-release proposal to create Integrated Health Homes (IHH)

Department of Homeland Security (DHS) “Public Charge Rule”
- Inadmissible and ineligible for a visa, ineligible for admission, and ineligible for adjustment of status, any alien who, in the opinion of the DHS, Department of State (DOS), or Department of Justice (DOJ) is likely at any time to become a “public charge”
- Rule now includes the receipt of non-cash benefits such as the Supplemental Nutrition Assistance Program (SNAP), Medicaid; and housing vouchers and other housing subsidies

Criminal Justice Involved Enrollees
- Trend toward suspending rather than terminating Medicaid enrollment while incarcerated
- Care coordination prior to release

Expanded access to Medication Assisted Treatment (MAT)
- Changes in prior authorization policies, increases in the number of qualified physicians under waiver, and expansion in access to and capacity of providers

Social Determinants of Health
- Attempts to address the root causes of poor health outcomes
- Housing, nutrition, transportation, employment, and trauma/violence

Mergers, Acquisitions, and Consolidation
- Centene, Illinicare, WellCare, Harmony, Meridian, Beacon Health Options
Institutions for Mental Disease (IMD)

Medicaid 1115 Waiver
- Ability for states to provide up to 30 days of SUD and mental health treatment in IMD during 12 month period
- 24 states approved waiver for SUD
- 5 states pending approval for SUD
- 1 state approved waiver for mental health
- 1 state pending approval for mental health

39 State Attorneys General have submitted a letter to Congressional leaders requesting full repeal of the IMD exclusion
Mental Health Parity and Addiction Equity Act

Department of Labor issued FAQs and forms relating to the 21st Century Cures Act and Non-Quantitative Treatment Limitations (NQTLs) on 9/5/19

- NQTLs are methods, processes, strategies, evidentiary standards, and other factors that plans and issuers may use

- FAQs address:
  - Application of guidelines to determine coverage of certain treatments
  - Prescription drug benefits
  - Reimbursement rates for non-physician practitioners
  - Provider admission to networks
  - Requesting information from plans
  - Provider directories

- Model disclosure form
  - Form to request documentation from an employer-sponsored health plan or a group or individual market insurer concerning treatment limitations
Privacy and Confidentiality

On August 26, 2019, SAMHSA published a Notice of Proposed Rulemaking (NPRM) for 42 CFR Part 2, the regulations governing the Confidentiality of Substance Use Disorder Patient Records

- Revised Definition of “Records” and “Information“ that Limits Application of Part 2
- Ability for Part 2 Program to share SUD information orally following patient consent and avoid redisclosure prohibition
- Downstream treating provider now able to “record” (verb) SUD information from an SUD “record” (noun) and not be subject to redisclosure prohibition
- Redisclosures by “lawful holders” for payment and health care operations clarified
- Disclosures by non-OTPs to central registries to avoid duplicating services permitted
- Disclosures to Prescription Drug Monitoring Programs (PDMPs) allowed but only with patient consent
- Modifying consent requirement to permit identifying entities (not individuals) for non-treatment purposes
- Broad expansion of definition of audit and evaluation
- Medical emergencies to include natural disasters
- Guidance on disclosures by patients to individual staff on personal electronic devices
- Extending time limits for court orders permitting undercover agents and informants
- In separate NPRM announce removal of “allegedly committed by the patient“ from court order requirements
Questions?

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Below are responses to additional frequently asked questions (FAQs) regarding implementation of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by the Affordable Care Act. The responses to FAQs also address implementation of the 21st Century Cures Act (Cures Act), the SUPPORT for Patient and Communities Act (Support Act), and the Employee Retirement Income Security Act (ERISA). These FAQs have been prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, “the Departments”). As with previously issued FAQs (available at https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act and www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs are designed to help people understand the law and benefit from it as intended through examples that illustrate the requirements of MHPAEA and its implementing regulations. While some of the fact patterns used as examples may be relatively uncomplicated, they should enable the public to identify and address important MHPAEA issues. These FAQs do not contain any new interpretations of MHPAEA, but instead provide additional examples of how the MHPAEA final regulations apply to different fact patterns to promote compliance.

Mental Health Parity and Addiction Equity Act of 2008 and the 21st Century Cures Act

In general, MHPAEA requires that the financial requirements (such as coinsurance and copays) and treatment limitations (such as visit limits) imposed on mental health or substance use disorder (MH/SUD) benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits in a classification.1

With regard to any nonquantitative treatment limitation (NQTL), the MHPAEA final regulations provide that a group health plan or health insurance issuer may not impose an NQTL with respect to MH/SUD benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used for substantially all medical/surgical benefits.

1 The six classifications of benefits defined in final rules implementing the requirements of MHPAEA are: (1) inpatient, in-network; (2) inpatient, out-of-network; (3) outpatient, in-network; (4) outpatient, out-of-network; (5) emergency care; and (6) prescription drugs. 26 CFR 54.9812-1(c)(2)(ii); 29 CFR 2590.712(c)(2)(ii); and 45 CFR 146.136(c)(2)(ii).
standards, or other factors used in applying the limitation to medical/surgical benefits in the same classification. MHPAEA also imposes certain disclosure requirements on group health plans and health insurance issuers offering group or individual health insurance coverage.

The Cures Act requires the Departments to solicit feedback and issue guidance regarding the disclosure and NQTL requirements of MHPAEA. Section 13001(b) of the Cures Act specifically requires that the Departments issue clarifying information and illustrative examples of methods that a plan or issuer offering group or individual health insurance coverage can use to disclose information in compliance with MHPAEA. Section 13001(b) also directs the Departments to issue clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that plans and issuers may use regarding the development and application of NQTLs such as:

1. Medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigational;
2. Limitations with respect to prescription drug formulary design, and use of “step therapy” protocols or “fail-first” policies;
3. Network admission standards (such as credentialing);
4. Factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy; and
5. Examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of NQTLs.

As part of the Departments’ implementation of the Cures Act, on June 16, 2017, the Departments issued MHPAEA compliance assistance guidance regarding benefits for eating disorder treatment.2

The Departments issued several additional documents related to MHPAEA on April 23, 2018, including an MHPAEA self-compliance tool to aid plans, issuers, and other stakeholders in understanding the requirements of MHPAEA, an action plan developed by HHS, DOL’s biannual report to Congress regarding MHPAEA implementation and enforcement efforts, and DOL’s fiscal year 2017 MHPAEA enforcement fact sheet.3 At the same time, the Departments

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also proposed two guidance documents with requests for comment. The first document was a model disclosure request form that could be used to request information from group health plans and health insurance issuers offering group or individual health insurance coverage. The second was, “Proposed FAQs about Mental Health and Substance Use Disorder Parity Implementation and The 21st Century Cures Act Part 39.”

In addition, on January 10, 2019, the DOL, in coordination with the Departments of HHS and the Treasury, hosted a roundtable discussion with stakeholders to discuss issues regarding MHPAEA implementation, including the proposed FAQs and model disclosure request form.

Commenters on the FAQs generally supported the Departments’ efforts to give additional guidance and compliance assistance. Stakeholders also shared important insights into certain compliance issues faced by plans and issuers, as well as issues faced by plan participants and their authorized representatives when they are seeking information about MH/SUD benefits. After considering these comments and making edits to clarify the guidance (including, where necessary, deleting language that commenters have identified as confusing or unclear), the Departments are issuing a final model disclosure request form and final FAQs Part 39 with clarifications.

The Departments intend to continue to provide additional MHPAEA implementation information on a rolling basis, including revised compliance program documents and updated enforcement data. For the most current information on MHPAEA, Cures Act, and Support Act implementation, see https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-and-substance-use-disorder-parity and https://www.cms.gov/cciio.

Nonquantitative Treatment Limitations

An NQTL is generally a limitation, often non-numeric, on the scope or duration of benefits for treatment. In developing and applying an NQTL, the regulations provide that a plan or issuer may consider a wide array of factors. For example, a plan can consider economic factors, such as high cost growth, or other factors such as the incidence of fraud with respect to services in a particular classification. In applying those factors, the NQTL analysis does not focus on whether the final result (for example, coverage denial rates) is the same for MH/SUD benefits and


4 A previous version of the model disclosure request form was issued by the Departments on June 16, 2017 with a request for public comment.

5 See 26 CFR 54.9812(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), 45 CFR 146.136(c)(4)(iii), example 8, outlining an illustrative list of factors that a plan uses to develop and apply a compliant NQTL.
medical/surgical benefits; instead, compliance depends on parity in development and application of the underlying processes and strategies. There should not be arbitrary or discriminatory differences in how a plan or issuer is applying those processes and strategies to medical/surgical benefits and MH/SUD benefits. Moreover, in the preamble to the MHPAEA final regulations (which reiterates guidance issued by the Departments in 2011), the Departments stated that it is unlikely that a reasonable application of the NQTL requirement would result in all MH/SUD benefits being subject to an NQTL in the same classification in which less than all medical/surgical benefits are subject to the NQTL.6 While similar or dissimilar outcomes between MH/SUD benefits and medical/surgical benefits with respect to, for example, benefit denial rates are NOT determinative of compliance, higher rates of denials for MH/SUD benefits may be viewed as a warning sign, or indicator of potential operational parity noncompliance. Vast differences in such rates can serve as a strong indicator of potential noncompliance. The following examples illustrate how to evaluate the factors used to develop and apply an NQTL in a variety of fact patterns.

Q1. My health plan document states that it excludes coverage for treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD benefits. For both medical/surgical benefits and MH/SUD benefits, the plan generally follows current medical evidence and professionally recognized guidelines on the efficacy of treatment. With respect to both medical/surgical benefits and MH/SUD benefits, the plan’s documents state that the plan excludes coverage for treatment as experimental for a given condition when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition, and fewer than two randomized controlled trials are available to support the treatment’s use with respect to the condition.

The plan defines Autism Spectrum Disorder as a mental health condition. More than one professionally recognized treatment guideline and more than two controlled randomized trials support the use of Applied Behavior Analysis (ABA) therapy to treat certain children with Autism Spectrum Disorder. The plan, in practice, excludes coverage for ABA therapy to treat children with Autism Spectrum Disorder under the rationale that the treatment is experimental or investigative. With respect to medical/surgical conditions, the plan covers treatment when supported by one or more professionally recognized treatment guidelines and two or more controlled randomized trials. Is this permissible under MHPAEA?

No. The plan’s application of the NQTL to MH/SUD benefits is not permissible because, in operation, the plan applies the NQTL more stringently to certain MH/SUD benefits than to

medical/surgical benefits. A medical management standard limiting or excluding benefits based on whether a treatment is experimental or investigative is an NQTL under MHPAEA.\textsuperscript{7} A group health plan or group or individual health insurance issuer may impose an NQTL on MH/SUD benefits if, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors used by the plan in applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in applying the NQTL to medical/surgical benefits in the same classification.

Although the plan as written purports to exclude experimental or investigative treatment for both MH/SUD and medical/surgical benefits using the same standards, in practice, it imposes this exclusion more stringently on certain MH/SUD benefits, as the plan excludes ABA therapy, despite the fact that professionally recognized treatment guidelines and the requisite number of randomized controlled trials support the use of ABA therapy to treat children with Autism Spectrum Disorder. Accordingly, the plan’s exclusion of certain MH/SUD benefits—in this case, for ABA therapy—does not comply with MHPAEA because the plan applies the NQTL more stringently to these MH/SUD benefits than to medical/surgical benefits.

To comply with MHPAEA, the plan must ensure that any processes, strategies, evidentiary standards, and other factors used to impose the exclusion are applied comparably to all medical/surgical and MH/SUD benefits in the relevant classification. This could be accomplished, in practice, by not excluding as experimental or investigative any treatment that has professionally recognized treatment guidelines defining clinically appropriate standards of care for the condition and for which at least two randomized controlled trials are available to support the treatment’s use with respect to the condition. To the extent the plan determines any treatment should be excluded after properly applying this standard, the plan should also document the factors relied upon to exclude the treatment on this basis.

Q2: My health plan documents state that the plan excludes coverage for treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD benefits. The plan defines experimental or investigative treatments as those with a rating below “B” in the Hayes Medical Technology Directory, with exceptions for certain treatments that have a rating of “C” only where an exception is determined to be medically appropriate. However, in operation, the plan reviews and covers certain treatments for medical/surgical conditions that have a rating of “C” only when an exception is determined to be medically appropriate.\textsuperscript{7} MHPAEA regulations at 26 CFR 54.9812-1(c)(4)(ii); 29 CFR 2590.712(c)(4)(ii); and 45 CFR 146.136(c)(4)(ii) contain an illustrative list of NQTLs that includes, among other things, medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative; formulary design for prescription drugs; network tier design; and plan methods for determining usual, customary, and reasonable charges.
appropriate, while denying all benefits for MH/SUD treatment that have a rating of “C” or below, without reviewing the treatments to determine whether exceptions are medically appropriate. Is this permissible under MHPAEA?

No. A medical management standard that limits or excludes benefits based on whether a treatment is experimental or investigative is an NQTL under MHPAEA.8 A plan or issuer may impose an NQTL on MH/SUD benefits if, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors used by the plan in applying its NQTL with respect to MH/SUD benefits are comparable to, and applied no more stringently than, those used in applying the NQTL with respect to medical/surgical benefits in the same classification.

Here, although the terms of the plan set forth the same evidentiary standard for MH/SUD benefits and medical/surgical benefits (defining experimental as having a Hayes Medical Technology Directory rating below “B,” with exceptions for those with a “C” rating where medically appropriate), the plan applies a different evidentiary standard, and the standard is more stringent for MH/SUD benefits than for medical/surgical benefits because claims for medical/surgical treatments with a “C” rating are reviewed to determine whether an exception is medically appropriate while claims for MH/SUD treatments with a “C” rating are denied without review by the plan to determine whether an exception might be medically appropriate. The fact that the plan ultimately denies some medical/surgical benefits that have a rating of “C” does not justify the total exclusion of treatments with a “C” rating for MH/SUD. Accordingly, the plan’s medical management standard does not comply with MHPAEA.

To comply with MHPAEA, the plan must apply the same exception for MH/SUD treatments in the same classification if the plan, in operation, provides an exception based on medical appropriateness for medical/surgical treatments. To ensure that its approach is compliant with MHPAEA and that it will be able to satisfy participants’ requests for documents, the plan should document in writing the availability and requirements of its exceptions process, as well as the factors relied upon in determining how the exception process applies to both MH/SUD and medical/surgical benefits.

Q3: My health plan documents state that the plan follows professionally recognized treatment guidelines when setting dosage limits for prescription medications, but the dosage limit set by my plan for buprenorphine to treat opioid use disorder is less than what professionally recognized treatment guidelines generally recommend. The dosage limits for prescription medications set by my plan with respect to medical/surgical benefits are not less than the limits such treatment guidelines recommend. Is this permissible under MHPAEA?

No. Medical management standards that limit or exclude benefits based on medical necessity, medical appropriateness, or other factors are NQTLs.9 Plans and issuers may impose dosage

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8 26 CFR 54.9812-1(c)(4)(ii); 29 CFR 2590.712(c)(4)(ii); 45 CFR 146.136(c)(4)(ii).
limits as a medical management technique with respect to prescription drug coverage under the
plan. Even though these medical management techniques may result in numerically expressed
limitations (such as dosage limits), the techniques are nevertheless NQTLs. The Departments’
regulations require that the processes, strategies, evidentiary standards, or other factors used in
applying an NQTL to MH/SUD prescription drug benefits (in this case, a dosage limit on
buprenorphine to treat opioid use disorder) must be comparable to, and applied no more
stringently than, the processes, strategies, evidentiary standards, or other factors used in applying
dosage limits to prescription drugs to treat medical/surgical conditions. If the plan follows the
dosage recommendations in professionally recognized treatment guidelines to set dosage limits
for prescription drugs in its formulary to treat medical/surgical conditions, it must also follow
comparable treatment guidelines, and apply them no more stringently, in setting dosage limits for
prescription drugs, including buprenorphine, to treat MH/SUD conditions.

The Departments are aware that, as an alternative to following professionally recognized
treatment guidelines, many plans and issuers use Pharmacy and Therapeutics (P&T) committees
to decide how to cover prescription drugs and evaluate whether to follow or deviate from
professionally recognized treatment guidelines for setting dosage limits. Although the use of
P&T committees to inform dosage limits for prescription drugs in this manner does not per se
violate MHPAEA, these processes must comply with MHPAEA’s NQTL standard in practice.
For example, if a plan or issuer deviates from nationally-recognized treatment guidelines for
buprenorphine/naloxone to treat opioid use disorder based on P&T committee recommendations
or reports, but does not deviate from such guidelines with respect to covering prescription drugs
to treat medical surgical benefits based on the recommendations of the P&T committee, then this
deviation should be evaluated for compliance with MHPAEA’s NQTL requirements. For
instance, the plan or issuer should determine (1) whether the expertise of the members of the
P&T committee in MH/SUD conditions is comparable to their expertise in medical/surgical
conditions (e.g., if a plan ensures that certain members of the P&T committee are board certified
in the area of medicine that will prescribe the treatment or drug in question, the plan must impose
this requirement comparably for benefits for both medical/surgical and MH/SUD treatments),
and (2) whether the committee’s evaluation of nationally-recognized treatment guidelines in
setting dosage limits for medications for both MH/SUD and medical/surgical conditions is
comparable.

Q4: My large group health plan or large group insurance coverage provides benefits for
prescription drugs to treat both medical/surgical and MH/SUD conditions but contains a
general exclusion for items and services to treat a specific mental health condition,
including prescription drugs to treat that condition. Is this permissible under MHPAEA?

Yes. Generally, MHPAEA requires that treatment limitations imposed on MH/SUD benefits
cannot be more restrictive than treatment limitations that apply to medical/surgical benefits. An
exclusion of all benefits for a particular condition or disorder, however, is not a treatment
limitation for purposes of the definition of “treatment limitations” as set forth in the MHPAEA
regulations. The MHPAEA regulations also provide that if a plan or issuer provides benefits for
a mental health condition or substance use disorder, benefits for that condition or disorder must
be provided in every classification in which medical/surgical benefits are provided. Because the
plan or coverage does not provide any MH/SUD benefits for that specific mental health condition in any classification, this exclusion is permissible under MHPAEA.10

**Q5: My health plan requires step therapy for both medical/surgical and MH/SUD inpatient, in-network benefits. The plan requires a participant to have two unsuccessful attempts at outpatient treatment in the past 12 months to be eligible for certain inpatient in-network SUD benefits. However, the plan requires only one unsuccessful attempt at outpatient treatment in the past 12 months to be eligible for inpatient, in-network medical/surgical benefits. Is this permissible under MHPAEA?**

Probably not, as it is unlikely that the plan’s analysis will support the application of this NQTL. Refusing to pay for a higher-cost therapy until it is shown that a lower-cost therapy is not effective (commonly known as “step therapy protocols” or “fail-first policies”) is an NQTL.11 The Departments’ regulations require that the processes, strategies, evidentiary standards, or other factors used in applying an NQTL to MH/SUD benefits must be comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to medical/surgical benefits. Although the same NQTL—step therapy—is applied to both MH/SUD benefits and medical/surgical benefits for eligibility for inpatient, in-network services, the requirement for two attempts at outpatient treatment to be eligible for inpatient, in-network SUD benefits is a more stringent application of the NQTL than the requirement for one attempt at outpatient treatment to be eligible for inpatient, in-network medical/surgical benefits. Unless the plan can demonstrate that evidentiary standards or other factors were utilized comparably to develop and apply the differing step therapy requirements for these MH/SUD and medical/surgical benefits, this NQTL does not comply with MHPAEA. If the plan can make that demonstration, the plan should document the factors relied upon to support the different step therapy protocols.

**Q6. My health plan documents state that in-network provider reimbursement rates are determined based on a variety of factors, including the providers’ required training, licensure, and expertise. For medical/surgical benefits, the difference in reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Technology (CPT) code12 varies based on a combination of factors such as the nature of the service, provider type (including demographics), market dynamics, and market need availability (demand). For MH/SUD benefits, the plan states that it varies reimbursement rates for non-physician practitioners for the same CPT code based on a combination of**

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10 Note that small group and individual health insurance coverage are generally subject to the requirement to provide essential health benefits, and the determination of whether certain benefits must be covered under the requirements for essential health benefits depends on the benefits in the applicable State’s essential health benefits benchmark plan. State law may also impose certain benefit mandates for large group insured coverage. See PHS Act section Sec. 2707(a); Patient Protection and Affordable Care Act section ACA Sec. 1302(a).

11 See 26 CFR 54.9812-1(c)(4)(ii); 29 CFR 2590.712(c)(4)(ii); 45 CFR 146.136(c)(4)(ii).

12 The CPT is a uniform numeric coding system maintained by the American Medical Association (AMA) consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. See HCPCS - General Information, available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html.
similar factors; however, despite these terms in the plan, the plan reduces the reimbursement rate by the same percentage for every CPT code for an MH/SUD service rendered by a non-physician practitioner. The plan does not do so with respect to medical/surgical providers. Is this permissible under MHPAEA?

No. While MHPAEA does not require a plan or issuer to pay identical provider reimbursement rates for medical/surgical and MH/SUD providers, a plan’s or issuer’s standards for admitting a provider to participate in a network (including the plan’s reimbursement rates for providers) is an NQTL. A plan or issuer may impose an NQTL if under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors used by the plan in applying its NQTL with respect to MH/SUD benefits are comparable to, and applied no more stringently than, those used in applying the NQTL with respect to medical/surgical benefits in the same classification. In other words, the plan or issuer must demonstrate that the methodology for developing and applying reimbursement rates under the plan is comparable and applied no more stringently for MH/SUD benefits when compared to the methodology for developing and applying reimbursement rates for medical/surgical benefits under the plan.

Here, the plan’s methodology for developing and applying reimbursement rates, in operation, is to reduce reimbursement rates by the same percentage for all non-physician practitioners providing MH/SUD services, while varying the reimbursement rate for non-physician practitioners providing medical/surgical services only when certain factors (e.g. the nature of the service, provider type, market dynamics, and demand) support such variance. The plan does not use a comparable process with respect to reimbursement of non-physician providers of medical/surgical and MH/SUD services. Accordingly, the plan’s use of this NQTL does not comply with MHPAEA.

To comply with MHPAEA, the plan must be able to demonstrate that it follows a comparable process in determining payment rates for non-physician providers for both medical/surgical and MH/SUD benefits.

Q7: In setting standards for provider admission to its network, my health plan considers the composition of current in-network providers to help ensure the plan has an adequate number of providers. With respect to its network of medical/surgical providers, the plan sets standards for provider admission in a manner that is calculated to ensure that participants and beneficiaries can schedule an appointment with a network provider within 15 days for non-urgent care, including, where appropriate, by increasing reimbursement rates and developing a process for accelerating participation in the network. The plan does not take comparable measures, where appropriate, to attempt to ensure an adequate network of MH/SUD providers. Is this permissible under MHPAEA?
No. Standards for provider admission to participate in a network, including reimbursement rates, are an NQTL. The Departments’ regulations require that the processes, strategies, evidentiary standards, or other factors used in applying an NQTL to MH/SUD benefits must be comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to medical/surgical benefits.

Here, in setting standards for provider admission to the network, the plan’s process to ensure the plan considers network adequacy with respect to providers of medical/surgical services is not comparable to its process with respect to providers of MH/SUD services.

The Departments note that greatly disparate results—for example, a network that includes far fewer MH/SUD providers than medical/surgical providers—are a red flag that a plan or issuer may be imposing an impermissible NQTL. Accordingly, further review of the NQTL may be required to determine parity compliance. MHPAEA does not require a plan or issuer to ensure that the numbers of MH/SUD and medical/surgical providers in the plan’s network are comparable, but the plan or issuer must undertake a comparable process and apply comparable strategies and evidentiary standards when developing and ensuring an adequate network. In this example, because the plan’s process for setting standards for MH/SUD provider admission to its network is not comparable to the process employed with respect to medical/surgical providers, the plan does not comply with MHPAEA.

To comply with MHPAEA, if the plan takes steps to ensure the plan has an adequate number of in-network medical/surgical providers, the plan must take comparable steps to ensure an adequate number of in-network MH/SUD providers, even if, following those steps, ultimately there are disparate numbers of MH/SUD and medical/surgical providers in the plan’s network.

Q8: My health plan generally covers medically appropriate treatments. The plan covers inpatient, out-of-network treatment outside of a hospital setting for medical/surgical conditions if the prescribing physician obtains prior authorization from the plan, the facility meets the licensing and certification requirements set by the plan, and the treatment is medically appropriate for the individual, based on clinically appropriate standards of care. The plan provides benefits for the treatment of eating disorders but

13 As stated in the preamble to the Departments’ final rules implementing MHPAEA, plan standards such as network adequacy (although not specifically enumerated in the illustrative list of NQTLs), must be applied in a manner that complies with the regulations. 78 FR 68239, 68246 (Nov. 13, 2013).
excludes all inpatient, out-of-network treatment outside a hospital setting for eating disorders, including non-hospital residential treatment (which it regards as an inpatient benefit). Is this permissible under MHPAEA?

No. The Departments’ regulations implementing MHPAEA define “mental health benefits” as benefits with respect to items or services for mental health conditions, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Section 13007 of the Cures Act clarified that if a group health plan or health insurance issuer offering group or individual health insurance coverage provides coverage for eating disorder benefits, including non-hospital residential treatment, those benefits must be offered consistent with the requirements of MHPAEA. Accordingly, the Departments have clarified that eating disorders are mental health conditions and, therefore, treatment of an eating disorder is a “mental health benefit” within the meaning of that term as defined by MHPAEA.\textsuperscript{15}

Plan or coverage restrictions based on facility type are NQTLs under the MHPAEA final regulations.\textsuperscript{16} A plan or issuer may impose an NQTL if, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors used by the plan or issuer in applying its exclusion with respect to MH/SUD benefits are comparable to and applied no more stringently than, those used in applying the NQTL to medical/surgical benefits in the same classification. In evaluating whether an exclusion of an intermediate level of care, including non-hospital residential treatment complies with MHPAEA, it must be determined if the intermediate level of care is assigned to the six benefit classifications in the same way for both medical/surgical and MH/SUD benefits.\textsuperscript{17} If so, then the basis for the exclusion (in this case, non-hospital residential treatment) in the classification must be reviewed to determine if the processes, strategies, evidentiary standards, and other factors used to apply the exclusion of MH/SUD benefits are comparable to and applied no more stringently than the processes, strategies, evidentiary standards, and other factors used in applying the NQTL to medical/surgical benefits in the same classification.

If a plan or issuer can articulate comparable and no more stringently applied processes, strategies, evidentiary standards, or other factors to exclude non-hospital residential treatment for MH/SUD benefits in certain circumstances, the plan or issuer may be able to demonstrate that the exclusion is consistent with the regulations under MHPAEA. However, in this example, the plan covers inpatient, out-of-network treatment outside a hospital for medical/surgical conditions


\textsuperscript{16} 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii).

\textsuperscript{17} See 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A). See also the preamble to the Departments’ final rules implementing MHPAEA, which states that if a plan or issuer classifies care in skilled nursing facilities or rehabilitation hospitals as inpatient benefits, then the plan or issuer must likewise treat any covered care in residential treatment facilities for MH/SUD services as an inpatient benefit. In addition, if a plan or issuer treats home health care as an outpatient benefit, then any covered intensive outpatient MH/SUD services and partial hospitalization must be considered outpatient benefits as well. 78 FR 68240, 68247 (Nov. 13, 2013).
so long as a prescribing physician obtains prior authorization from the plan, the treatment is medically appropriate for the individual, and the facility meets the licensing and certification requirements set by the plan, while the plan unequivocally excludes all inpatient, out-of-network treatment outside a hospital (in this case, non-hospital residential treatment) for eating disorders. This restriction on non-hospital residential treatment for eating disorders is not comparable to the plan’s coverage restrictions for inpatient treatment outside a hospital for medical/surgical conditions, which are less stringent. This exclusion does not comply with MHPAEA.

A plan or issuer may rely on one or more factors to develop and apply an NQTL, provided the factors are comparable and no more stringently applied to MH/SUD benefits as compared to medical/surgical benefits (in this case, both medical appropriateness of the service, as well as the credentials of the facility). Such factors can be a mix of statistical, clinical or other factors, such as high incidence of fraud with respect to services in a particular classification.\textsuperscript{18} The plan or issuer should document any factors relied upon in developing and applying this NQTL.

**Disclosures with Respect to MH/SUD Benefits**

The MHPAEA final regulations provide express disclosure requirements. Specifically, the criteria for medical necessity determinations with respect to MH/SUD benefits must be made available by the plan administrator or the health insurance issuer to any current or potential participant, beneficiary, or contracting provider upon request.\textsuperscript{19} In addition, under MHPAEA, the reason for any denial of reimbursement or payment for services with respect to MH/SUD benefits in the case of any participant or beneficiary must be made available to the participant or beneficiary.\textsuperscript{20}

The Departments also explained in the preamble to the final regulations that, in addition to these specific disclosure obligations under MHPAEA, ERISA’s general disclosure obligation in section 104(b) and the accompanying disclosure regulation at 29 CFR 2520.104b-1 provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. A document that specifies procedures, formulas, methodologies, or schedules that are applied in determining or calculating a participant’s benefit under the plan constitutes an instrument under which the plan is established or operated.\textsuperscript{21} Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and MH/SUD benefits, as well as the processes, strategies, evidentiary standards, and other factors

\textsuperscript{18} See 26 CFR 54.9812-1(c)(4)(iii), Example 8; 29 CFR 2590.712(c)(4)(iii), Example 8, and 45 CFR 146.136(c)(4)(iii), Example 8.
\textsuperscript{19} 26 CFR 54.9812-1(d)(1), 29 CFR 2590.712(d)(1), 45 CFR 146.136(d)(1) and 147.160.
used to apply an NQTL with respect to medical/surgical benefits and MH/SUD benefits under the plan. In addition, 29 CFR 2560.503-1, 26 CFR 54.9815-2719, 29 CFR 2590.715-2719 and 45 CFR 147.136 set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant’s claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and MH/SUD benefits, as well as documents reflecting the processes, strategies, evidentiary standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and MH/SUD benefits under the plan.

Contemporaneous with the issuance of the MHPAEA final regulations, the Departments published FAQs addressing a group health plan’s disclosure obligations under MHPAEA and ERISA generally, as well as the specific information a participant is entitled to receive when a claim for MH/SUD benefits has been denied. In addition to reiterating that “instruments under which the plan is established or operated” under ERISA section 104 includes documents with information on medical necessity criteria for both medical/surgical and MH/SUD benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply an NQTL, the FAQs noted that other provisions of Federal law require such disclosures.

On October 27, 2016, the Departments issued Affordable Care Act Implementation FAQs Part 34, which, among other things, solicited feedback regarding disclosures with respect to MH/SUD benefits under MHPAEA and other laws. In the FAQs, the Departments indicated that they had received questions and suggestions regarding disclosures with respect to NQTLS. This feedback included requests for model forms that group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on their behalf could use to request relevant disclosures. The Departments initially proposed a model form on June 16, 2017 and solicited comments. After reviewing the comments, the Departments proposed a revised model form on April 23, 2018 and again solicited comments. The Departments are finalizing this model disclosure request form, with some clarifications in response to comments. Use of the form by participants, beneficiaries, and enrollees is optional and is meant to facilitate the ability of

22 A document, record, or other information is considered “relevant” for a group health plan under 29 CFR 2560.503-1(m)(8) if it (i) was relied upon in making the benefit determination; (ii) was submitted, considered, or generated in the course of making the benefit determination, without regard to whether such document, record, or other information was relied upon in making the benefit determination; (iii) demonstrates compliance with the administrative processes and safeguards required to ensure and verify that claims are decided in accordance with governing plan documents and consistently with similar claims; or (iv) constitutes a statement of plan policy or guidance concerning the denied treatment option or benefit for the claimant’s diagnosis, without regard to whether such advice or statement was relied upon in making the benefit determination.

covered individuals to request information disclosure in certain circumstances. The model form is set forth at the end of these FAQs.

The following FAQs provide examples of how certain provisions of Federal law may require disclosures relevant to MH/SUD benefits.

**Q9: I wish to request information from my ERISA-covered group health plan regarding limitations that may affect my access to MH/SUD benefits. Do the Departments have any materials that may assist me?**

Under ERISA, plans are required to provide summary plan descriptions (SPDs) that describe, in terms understandable to the average plan participant, the rights, benefits, and responsibilities of participants and beneficiaries. Plans are also required to provide a Summary of Benefits and Coverage (SBC) that includes, among other elements, a description of the coverage; the exceptions, reductions, and limitations of the coverage and the cost-sharing provisions of the coverage. The Departments encourage participants and beneficiaries to first consult their SBC, as well as their SPD, for information on how their plan covers MH/SUD benefits. If you do not have an SPD or SBC, consider requesting them. Generally, the plan is required to give participants and beneficiaries copies of these documents on request.

The Departments also developed a model form that individuals, or their authorized representatives may—but are not required to—use to request information that may affect their MH/SUD benefits. This model form can be used for general requests for information regarding MH/SUD benefits and treatment limitations, such as a request for the relevant portions of the SPD or plan document. This model form can also be used to obtain documentation after an adverse benefit determination involving MH/SUD benefits to support an appeal. Furthermore, plans and issuers may find that making this model disclosure form available to their participants or enrollees may help clarify and streamline requests for information. Use of the form is optional for participants, and plans and issuers may use their own disclosure forms to help facilitate disclosure requests. The model form is set forth at the end of these FAQs.

**Q10: My ERISA-covered group health plan utilizes a provider network and provides a provider directory with its SPD. The entire directory is out of date and inaccurate. Is this permissible?**

No. Under 29 CFR 2520.102-3(j)(3) of the DOL’s regulations, if an ERISA-covered plan utilizes a network, its SPD must provide a general description of the provider network, as well as the composition of the provider network. The list of providers may be distributed as a separate document that accompanies the plan’s SPD if it is furnished automatically and without charge and the SPD contains a statement to that effect. The list of providers, whether set forth in the SPD, or separately, must be up-to-date, accurate, and complete (using reasonable efforts).

Qualified Health Plan (QHP) issuers are also obligated to comply with 45 CFR 156.230(b)(2) of HHS’s regulations that requires the issuer to publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, and the provider’s location, contact information, specialty, medical group, and any institutional...
affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Health Insurance Marketplace, HHS, and the Office of Personnel Management (OPM).

Q11: Are ERISA-covered plans and issuers that utilize provider networks permitted to provide a hyperlink or URL address in enrollment and plan summary materials for a provider directory where information related to network providers, including MH/SUD providers, can be found?

Yes. ERISA-covered plans must provide an SPD that describes provisions related to the use of network providers, and the composition of the provider network, under ERISA section 102 and DOL’s implementing regulations. Such information may be provided as a separate document and, in many circumstances, may be provided electronically (for instance in a hyperlink or URL address).24

Furthermore, under PHS Act section 2715 and its implementing regulations, for group health plans and health insurance issuers offering group or individual health insurance coverage that maintain one or more networks of providers, the plan or issuer must provide a SBC that includes an Internet address (or similar contact information) for obtaining a list of network providers.25

Finally, as stated in Q&A-10, QHP issuers must make their provider directories available online. For plan years beginning on or after January 1, 2016, a QHP issuer must publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, and the provider’s location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, and OPM.26

24 29 CFR 2520.104b-1(c).
26 45 CFR 156.156.230(b)(2).
MODEL DISCLOSURE FORM

FORM TO REQUEST DOCUMENTATION FROM AN EMPLOYER-SPONSORED HEALTH PLAN OR A GROUP OR INDIVIDUAL MARKET INSURER CONCERNING TREATMENT LIMITATIONS

Background: This is a tool to help you request information from your employer-sponsored health plan or your group or individual market insurer regarding treatment limitations that may affect your access to mental health or substance use disorder benefits. You can use this form to request:

- **General information** about treatment limitations, like your plan’s preauthorization policies for both medical/surgical and mental health treatment.
- **Specific information** about why benefits were denied. For example, you can ask about the criteria for “failure to show medical necessity” that your health insurance company may have used to deny your claim.

Your plan or insurer is required by law to provide you this information in certain instances. In some cases, a request can result in more information than you may want. Talk to your plan or insurer about what documents you wish to request, and, if you prefer, how you can receive the documents electronically.

Under a federal law called the Mental Health Parity and Addiction Equity Act (MHPAEA), many health plans and insurers must make sure that there is “parity” between mental health and substance use disorder benefits, and medical and surgical benefits. This generally means that financial requirements and treatment limitations applied to mental health or substance use disorder benefits cannot be more restrictive than the financial requirements and treatment limitations applied to medical and surgical benefits. The types of limits covered by parity protections include:

- Financial requirements—such as deductibles, copayments, coinsurance, and out-of-pocket limits; and
- Treatment limitations—such as limits on the number of days or visits covered, or other limits on the scope or duration of treatment (for example, being required to get prior authorization).

If you, a family member, or someone you are helping obtains health coverage through a private employer health plan, federal law requires the plan to provide certain plan documents about your or their benefits, including coverage limitations on those benefits, on request. For example, you may want to obtain documentation as to why your health plan is requiring pre-authorization for visits to a therapist before it will cover the visits. Generally, private employer plans must provide the documents within thirty (30) calendar days of the plan’s receipt of your request. **Contact your health plan or health insurance company directly to submit your request.**

This form is designed to help you request information from your plan about treatment limitations. Many common types of treatment limits are listed on this form. If the type of treatment limitations being imposed by your plan does not appear on the list, you may insert a
description of the treatment limitation about which you would like more information under “Other.”

**Instructions:** Complete the attached form to request general information from your plan or insurer about treatment limitations or specific information about why your mental health or substance use disorder benefits were denied. This information may help you appeal a claim denial, but you must separately initiate the plan’s general review and appeals process if you want to appeal the claim denial with your plan or insurer. You do not have to use this form to request information from your plan. Consult your summary plan description (SPD) or certificate of coverage to see how to request information from the plan, or how to appeal a denied claim.

If you are helping someone request information about his/her health coverage, a plan or insurer may require you to submit, with your request for information, additional documentation signed by the person you are helping (if you have not already done so).

If you have any questions about this form and you are enrolled in a private employer health plan, you may visit the Employee Benefits Security Administration’s (EBSA’s) website at [www.dol.gov/ebsa](http://www.dol.gov/ebsa) for answers to common questions about private employer health plans. You may also contact EBSA electronically at [www.askebsa.dol.gov](http://www.askebsa.dol.gov) or call toll free 1-866-444-3272.

You can also use this form if you are enrolled in coverage that is not through a private employer health plan—for example, if you have individual health coverage or coverage sponsored by a public sector employer, like a city or state government. You may contact the Centers for Medicare & Medicaid Services (CMS) at phig@cms.hhs.gov or 1-877-267-2323 ext. 61565 for questions about your individual health coverage or public sector health plan.
PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 1210-0138. The time required to complete this information collection is estimated to average 5 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Labor, Employee Benefits Security Administration, Office of Policy and Research, Attention: PRA Clearance Officer, 200 Constitution Avenue, N.W., Room N-5718, Washington, DC 20210 or email ebsa.opr@dol.gov and reference the OMB Control Number 1210-0138.
Date: _____________________

Mental Health and Substance Use Disorder Parity Disclosure Request

**NOTE:** This disclosure request form is NOT designed to initiate a formal claim for benefits or an appeal of a denied claim; however, the information obtained through this form may help you appeal a medical claim denial with respect to your mental health and substance use disorder benefits. Submitting this form is voluntary and does NOT replace your health plan’s claims or appeals process.

To: ______________________________ [Insert name of the health plan or issuer]

(If you are a provider or another representative who is authorized to request information for the individual enrolled in the plan, provide the information below.)

I am an authorized representative requesting information for the following individual enrolled in the plan:

Attached to this request is an authorization signed by the enrollee.

*(Complete this section if you’re requesting general information about treatment limitations.)*

**General Information Request**

☐ I am requesting information concerning the plan’s limitations related to coverage for:

☐ Mental health and substance use disorder benefits, generally.
☐ The following specific treatment for my mental health condition or substance use disorder: ____________________________

*(Complete this section if you’re requesting specific information about limitations that led to a denial of benefits.)*

**Claim/Denial Information Request**

☐ I was notified on __________ [Insert date of denial] that a claim for coverage of treatment for __________________ [Insert mental health condition or substance use disorder] was, or may be, denied or restricted for the following reason[s] shown immediately below:
(Based on your understanding of the denial of, limitation on, or reduction in coverage, check all that apply)

- I was advised that the treatment was not medically necessary.
- I was advised that the treatment was experimental or investigatory.
- The plan requires authorization before it will cover the treatment.
- The plan requires ongoing authorizations before it will cover my continued treatment.
- The plan is requiring me to try a different treatment before authorizing the treatment that my doctor or therapist recommends.
- The plan will not authorize any more treatments based on the fact that I failed to complete a prior course of treatment.
- The plan’s prescription drug formulary does not cover the medication my doctor is prescribing.
- My plan covers my mental health or substance use disorder treatment, but does not have any reasonably accessible in-network providers for that treatment.
- I am not sure whether my plan’s calculation of payment for out-of-network services, such as its methods for determining usual, customary and reasonable charges, complies with parity protections.
- Other: (Specify basis for denial of, limitation on, or reduction in coverage):

Because my health coverage is subject to the parity protections, financial requirements or treatment limitations cannot be applied to mental health or substance use disorder benefits unless those limits are comparable to financial requirements or treatment limitations applied to medical and surgical benefits. Therefore, for the limitations or terms of the benefit plan specified above, within thirty (30) calendar days from the date of receipt of this request, I request that the plan:

☐ 1. Provide the specific plan language regarding the limitation(s) and identify the medical/surgical and mental health or substance use disorder benefits to which it applies in the relevant benefit classification described in the regulations under the Mental Health Parity and Addiction Equity Act;
☐ 2. Identify the factors used in the development of the limitation(s) (examples of factors include, but are not limited to, excessive utilization, recent medical cost escalation, high variability in cost for each episode of care, and safety and effectiveness of treatment);
3. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above. Examples of evidentiary standards include, but are not limited to, the following:

- Excessive utilization as defined by two standard deviations above average utilization per episode of care;
- Recent medical cost escalation as defined by medical costs for certain services increasing 10% or more per year for 2 years;
- High variability in cost per episode of care as defined by episodes of outpatient care being 2 standard deviations higher in total costs than the average cost per episode 20% or more of the time in a 12-month period; and
- Safety and efficacy of treatment modality as defined by 2 random clinical trials required to establish that a treatment is not experimental or investigative;

4. Identify the methods and analysis used in the development of the limitation(s); and

5. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

Printed Name of Individual Enrolled in the Plan or his or her Authorized Representative

____________________________

Signature of Individual Enrolled in the Plan or his or her Authorized Representative

____________________________

Member Number (number assigned to the enrolled individual by the Plan)

____________________________

Claim Number (if seeking information regarding a specific claim)

____________________________

Address

____________________________

Date

____________________________

E-mail address (if email is a preferred method of contact)
SAMHSA Releases Proposed Revisions to 42 CFR Part 2
The Federal Regulations Governing Substance Use Disorder Confidentiality

By
Gerald (Jud) E. DeLoss
IABH General Counsel
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Yesterday afternoon the US Department of Health and Human Services and the Substance Abuse and Mental Health Services Administration released a Notice of Proposed Rulemaking (NPRM) to modify 42 CFR Part 2 (Part 2), the regulations governing the confidentiality of substance use disorder (SUD) patient records. The NPRM makes many proposed changes to Part 2 but the majority of those revisions do not directly impact SUD treatment programs. Those critical provisions impacting SUD treatment programs covered by Part 2 are set forth first. Other important changes to the regulations are set forth below.

Key Changes for SUD Treatment Providers

1. Guidance on Employee Use of Personal Devices and Accounts

The NPRM outlines guidance on employee usage of personal electronic devices (cell phones, laptops) and personal accounts (email). SAMHSA outlined scenarios in which a patient contacted a treatment facility employee, trainee, or volunteer on their personal cell phone and how Part 2 governs the maintenance of that information as well as what should be done in the event the Part 2 program discontinues operation.

According to SAMHSA, if an employee/trainee/volunteer receives a communication from a patient on his or her personal device that is not regularly used for work purposes, then she or he should:

- Forward any patient information to the Part 2 program’s authorized channel
- Immediately delete the communication (text or email)
- Only respond to the patient via the Part 2 program’s authorized channel
- Respond directly from personal device/account only if necessary to protect the patient

In the event that the Part 2 program discontinues operation, the personal device or account would not be subject to the requirements of section 2.19 which mandate the wiping or sanitization of electronic records within one year of the program’s discontinuation.

2. Changes to Consent Requirements

The NPRM also modifies the requirements under section 2.31 that specify the requirements for a valid consent. In order to permit disclosures to third parties that are not health care providers, the consent provision spelling out the recipient of the record (the “To Whom” provision) now allows for the consent to state either the name of the individual(s) or entity or entities to whom the disclosure is made. This provision was added to assist patients in sharing information with third
parties such as the Social Security Administration for determination of benefits, or to a sober living facility or halfway house for non-medical services. Limits remain for the disclosure of records to health information exchanges and research institutions utilizing a general designation.

3. **Disclosures to PDMPs**

SAMHSA had previously issued guidance that opioid treatment programs (OTPs) should not share information with prescription drug monitoring programs (PDMPs). The NPRM announces a change in SAMHSA’s position and a move towards permitting the sharing of SUD records with PDMPs. SAMHSA now believes that permitting Part 2 programs and OTPs to share dispensing data with PDMPs would allow for greater patient safety, better treatment, and better care coordination. Under the proposed rule, OTPs and lawful holders of their records may now report the required data to PDMPs when dispensing medications. However, the disclosure would require patient consent to do so.

4. **Medical Emergencies**

Currently Part 2 permits a program to share information without patient consent in the event of a medical emergency. In the past this exception has been interpreted to apply only to disclosures for a clinical emergency where sharing of SUD information is necessary to provide life-saving care.

The NPRM proposes to expand the definition of a medical emergency to include natural disasters and events in which a Part 2 program is closed and unable to provide services or obtain written consent from the patient. The state of emergency would have to be declared by state or federal authorities and would only last until the program could resume operation.

5. **Disclosures for Research**

Previously Part 2 only permitted disclosures for research purposes pursuant to patient consent or to a HIPAA covered entity or business associate or in the event that the recipient is subject to the Common Rule, which protects human research subjects.

The NPRM broadens the research exception to allow research disclosures without consent from a HIPAA covered entity or business associate to third parties who are not HIPAA covered entities or business associates and not subject to the Common Rule, provided that any such data would only be disclosed in accordance with HIPAA. In addition, research disclosures may be made to the members of a workforce of a HIPAA covered entity for purposes of employer-sponsored research, where the covered entity requires the workforce to comply with HIPAA or the Common Rule. Finally, research disclosures would be permitted to recipients who are covered by Food and Drug Administration (FDA) regulations for the protection of human research subjects in clinical investigations, where done so in compliance with applicable FDA regulations.

6. **Audit and Evaluation**

In what may be the biggest area of impact for SUD treatment providers and facilities subject to Part 2, SAMHSA has greatly expanded the activities which will be considered audits or evaluations
under section 2.53. That section permits a Part 2 program to share patient records with an entity conducting audits or evaluations without the need for patient consent, subject to certain confidentiality safeguards.

The NPRM expands the types of activities that may be conducted under this section without patient consent and expressly includes a variety of recipients of the records that may not have been traditionally considered to be audit and evaluation entities. SAMHSA’s stated goal was to broaden the exception beyond individual program performance to allow for evaluation across programs to identify if any agency or payor action was necessary to improve care and outcomes. As such, the NPRM permits government agencies and third-party payors access to patient records without consent for periodic reviews and evaluations for purposes such as identifying agency or health plan actions or policy changes aimed at improving outcomes for SUD patients, targeting resources for better patient care, or adjusting Medicaid or other insurance to provide adequate coverage or payment.

While these new exceptions would not permit the sharing of Part 2 records for care coordination, it would allow disclosures without consent for activities related to reviews of appropriateness of treatment, medical necessity, and utilization. The NPRM also clarifies that sharing of SUD records within an organization with different service lines or components for audits and evaluations by the organization of the non-Part 2 service lines or components is permissible.

The NPRM also confirms that quality assurance entities for purposes of the audit and evaluation exception include accreditation or certification bodies that focus on quality assurance. Finally, the NPRM permits the sharing of records to federal, state, and local government agencies as well as their contractors, subcontractors, and legal representatives, for purposes of conducting legally-mandated audits and evaluations.

Other Proposed Revisions

In addition to those areas directly impacting SUD treatment programs as described above, the NPRM makes a host of proposed modifications that allow for the greater flow of information by the downstream recipients of the records – deemed “lawful holders” for treatment, payment, and health care operations purposes.

1. Revised Definition of “Records”

The NPRM proposes to limit the application of Part 2 to only what SAMHSA has defined as a “record”. Thus, the term “information” is no longer utilized when addressing the sharing of Part 2 covered data by downstream recipients. For example, it would become permissible for a physician who had received SUD treatment information from a Part 2 program pursuant to a valid consent to include that information within her or his physician-generated record and not have to prevent against redisclosure of his/her record under Part 2, if the Part 2 program had communicated the data to the physician orally. Where the data had been shared via a “record” then the Part 2 protections against redisclosure would apply. However, now under the NPRM if the Part 2
program shared the SUD information via a telephone call or an in-person consultation, the information would no longer be protected under Part 2 if the recipient included that information in the record that she or he generated as part of the direct treatment interaction with the patient. This modification would have the effect of permitting the physician to share or redisclose the physician-generated record with third parties if allowed under HIPAA or applicable state law.

In a further departure from existing law, the NPRM proposes to also permit downstream treating providers to record information about an SUD and treatment as part of the patient encounter into his or her self-generated record and no longer be subject to the redisclosure prohibition. In other words, the treating provider could take the “information” out of the Part 2 “record”, create the treating provider’s own new patient record, and share that new record in accordance with HIPAA and applicable state law – but not be subject to Part 2’s limitation on redisclosure. Those Part 2 records that the physician received in paper or electronic form would need to remain under Part 2 protections and would be segregated or segmented to avoid inadvertent redisclosure. This provision is unclear and the description provided by Assistant Secretary McCance-Katz on this subject did not clarify it fully so it remains to be seen how far SAMHSA will permit downstream treating providers to go in recording information from a Part 2 record without falling under its restrictions and protections.

2. Further Revisions to Redisclosure Prohibition

The NPRM also proposes to remove “superfluous” language that stated patient information protected by Part 2 included “that identifies a patient as having or having had a [SUD] either directly, by reference to publicly available information, or through verification of such identification by another person”. SAMHSA stated that the deletion of this language was in alignment with the Part 2 protections against redisclosure which should only apply to Part 2 “records” and not “information” in the general sense. As such, the Part 2 record would remain protected and not subject to redisclosure without patient consent, but information gleaned from the record and placed into the recipient’s own record would not necessarily be protected under Part 2.

3. Disclosures by Lawful Holders Without Consent

The 2018 modifications to Part 2 allow for a lawful holder of Part 2 records to share them with their contractors, subcontractors, and legal representatives, without patient consent but only for purposes of payment and health care operations. The 2018 modification did not spell out all permitted payment and operations activities.

In the NPRM, SAMHSA now expressly sets forth each payment and health care operation activity permitted under this exception to the consent requirement and also includes any other payment or health care operations activities not expressly prohibited. This means is that recipients of Part 2 records pursuant to a valid patient consent would now be able to share those records with contractors, subcontractors, and legal representatives without obtaining an additional patient consent for what might be considered a redisclosure. However, this new provision would not permit the sharing of Part 2 records for care coordination or case management.
This proposed revision will likely result in third parties, such as payors or MCOs, being able to share Part 2 records with their contractors and subcontractors for payment and operations purposes without needing to obtain a new patient consent for each of those disclosures/rediscoveries.

4. Disclosures to Prevent Multiple Enrollments

The NPRM proposes to expand Part 2 to make non-OTP providers with a treating provider relationship with the patient eligible to query a central registry to determine whether that patient is already receiving opioid treatment through a member program. The addition of non-OTPs to the list of eligible entities for querying of central registries is expected to prevent duplicative enrollments and prescriptions for excessive opioids.

5. Undercover Agents and Informants

Finally, the NPRM proposes to lengthen the effective date of court orders authorizing placement of an undercover agent or informant in a Part 2 program from 6 months to 12 months, with the opportunity to further extend the period with a new court order. In addition, the NPRM proposes to commence the 12-month period upon placement of the undercover agent or informant – rather than commencing upon entry of the court order, which can take place a great length of time before the agent or informant is placed at the program.

Comments

Interested parties and the public are invited to submit comments on the NPRM. To ensure consideration, the comments must be submitted no later than 60 days following publication of the NPRM in the Federal Register, which is expected to take place on August 26, 2019. The most convenient method to submit comments is electronically at www.regulations.gov.