NEW YORK STATE
DEPARTMENT *of*
FINANCIAL SERVICES

Andrew M. Cuomo
Governor

Benjamin M. Lawsky
Superintendent

Insurance Circular Letter No. 5 (2014)
June 4, 2014

TO: **All Insurers Authorized to Write Accident and Health Insurance in New York State, Article 43 Corporations, and Health Maintenance Organizations ("HMOs") (collectively, "issuers")**

RE: **Impact of Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA"), Affordable Care Act ("ACA"), and the MHPAEA Final Rule on Mental Health and Substance Use Disorder Benefits in New York's Health Insurance Market.**

STATUTORY AND REGULATORY REFERENCES: 42 U.S.C. 300gg-1, et al.; 42 U.S.C. 18001, et al.; 45 C.F.R. Parts 146 and 147; and N.Y. Ins. Law §§ 3103, 3201, 3221, 4303, and 4308 and Article 49

The purpose of this circular letter is to provide guidance to issuers about the impact of the federal MHPAEA on New York's health insurance market in light of the ACA and the issuance of the final rule implementing MHPAEA, which applies to group health plans and health insurance issuers for plan or policy years beginning on or after July 1, 2014.

This circular letter supersedes Circular Letter No. 20 (2009) and Supplement No. 1 to Circular Letter No. 20 (2009), both of which are hereby withdrawn.

I. <u>Background</u>

When enacted in 2008, MHPAEA applied to any group health plan, and any health insurance coverage offered in conjunction with such a plan, that had more than 50 total employees ("large group health plan"), and applied to plan years beginning on or after October 3, 2009. While MHPAEA did not require plans to cover treatment for mental health conditions ("MH") or substance use disorders ("SUD"), it provided that if such conditions or disorders were covered, then they had to be covered at the same level as coverage under the plan for surgical and medical conditions.

On February 2, 2010, the United States Departments of Treasury, Labor, and Health and Human Services published an interim final rule further explaining and clarifying MHPAEA. On November 13, 2013, those Departments published a final rule, 45 C.F.R. Parts 146 and 147, following consideration of comments received in response to the interim final rule.

On March 23, 2010, President Barack Obama signed the ACA into law. The ACA requires individual and small group health insurance policies and contracts (collectively, "policies") to provide

essential health benefits ("EHB"), including MH/SUD benefits. Additionally, as part of the ACA, Congress amended MHPAEA to extend its applicability to individual health insurance policies.

II. Impact of ACA and MHPAEA on Coverage in New York

A. ACA

Although MHPAEA continues to exempt from its requirements group health insurance policies issued to small employers, 45 C.F.R. § 146.136(f) clarifies that an issuer offering non-grandfathered health insurance coverage in the individual or small group market providing MH/SUD benefits as part of EHB must comply with MHPAEA to satisfy the ACA's requirement to provide EHB. Thus, any individual or small group health insurance coverage delivered or issued for delivery in New York that is required to include EHB also must comply with the requirements of MHPAEA.

B. MHPAEA and 45 C.F.R. Part 146

1. Benefit Classifications

MHPAEA requires benefits for MH/SUD coverage to be placed in one of six classifications: inpatient in-network; inpatient out-of-network; outpatient in-network; outpatient out-of-network; emergency care; and prescription drugs. See 45 C.F.R. § 146.136(c)(1)(i). In addition, 45 C.F.R. § 146.136(c)(3)(iii)(C) permits the outpatient classification to be separated into two sub-classifications, office visits and all other outpatient services. Determining whether specific MH/SUD benefits are in compliance with MHPAEA involves analyzing them in comparison to the medical/surgical benefits in the same classification. Thus, inpatient MH/SUD benefits are to be compared to inpatient medical/surgical benefits; prescription drugs to treat MH/SUD are to be compared to the prescription drug benefit to treat medical/surgical conditions; and so forth.

Furthermore, 45 C.F.R. § 146.136(c)(3)(iii)(B) recognizes sub-classifications based on tiered networks. It permits policies with multi-tiered provider networks to divide their benefits furnished on an in-network basis into sub-classifications that reflect the network tiers, if the tiering is: (1) based on reasonable factors (such as quality, performance, and market standards); and (2) done without regard to whether the provider is providing medical/surgical services or MH/SUD services.

2. Financial Requirements and Quantitative Treatment Limitations

Issuers that provide medical/surgical benefits and MH/SUD benefits must ensure that the financial requirements and quantitative treatment limitations applicable to MH/SUD are no more restrictive than the predominant financial requirements and treatment limitations applied to substantially all medical and surgical benefits covered by the policy. See 45 C.F.R. § 146.136(c)(2)(i). Financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See 45 C.F.R. § 146.136(a).

A type of financial requirement or quantitative treatment limitation applies to substantially all medical/surgical benefits in a classification if it applies to at least two-thirds of all medical/surgical benefits in that classification. See 45 C.F.R. § 146.136(c)(3)(i)(A). If the type of financial requirement or quantitative treatment limitation does not meet the two-thirds threshold, then the policy may not impose that particular type of financial requirement or quantitative treatment limitation on MH/SUD benefits. See id. For instance, a policy that imposes copayments on only one-half of the inpatient in-

network medical/surgical benefits may not impose copayments on inpatient in-network MH/SUD benefits.

If the policy imposes a type of financial requirement or quantitative treatment limitation on at least two-thirds of the medical/surgical benefits in a classification, then the issuer must determine the predominant level of that type of financial requirement or quantitative treatment limitation for the medical/surgical benefits in that classification. See 45 C.F.R. § 146.136(c)(3)(i)(B)(1). The predominant level of the financial requirement or quantitative treatment limitation is the level that applies to more than one-half of the medical/surgical benefits in that classification. See id. For instance, assuming that copayments apply to substantially all medical/surgical benefits, if a policy imposes a $50 copayment on one-quarter of the outpatient in-network medical/surgical benefits and a $25 copayment on three-quarters of the outpatient in-network medical/surgical benefits, then the issuer only may impose a $25 copayment on outpatient in-network MH/SUD benefits.

If no single level applies to more than one-half of the medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, then the issuer may combine levels until the combination of levels applies to more than one-half of the medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. See 45 C.F.R. § 146.136(c)(3)(i)(B)(2). In such case, the least restrictive level within the combination is considered the predominant level of that type of classification. See id.

With respect to financial requirements, the determination of the portion of medical/surgical benefits in a classification subject to a financial requirement is based on the dollar amount of all plan payments for the medical/surgical benefits in the classification expected to be paid under the policy for the plan year. See 45 C.F.R. § 146.136(c)(3)(i)(E).

An issuer with a policy that subjects MH/SUD benefits to a specialty office visit copayment must provide written assurance to the Superintendent of Financial Services that the policy is in compliance with MHPAEA before the Superintendent will approve the policy.

3. Out-of-Network Coverage

Policies that provide coverage for out-of-network medical/surgical services must provide coverage for out-of-network MH/SUD services. See 45 C.F.R. § 146.136(c)(2)(ii)(B).

4. Nonquantitative Treatment Limitations

Issuers may not impose nonquantitative treatment limitations ("NQTLs") with respect to MH/SUD in any classification unless any processes, strategies, evidentiary standards, or other factors used in applying the limitations are comparable to and no more stringent than the processes, strategies, evidentiary standards, or other factors used in applying the limitations to the medical/surgical benefits in the classification. NQTLs include medical management standards, medical necessity determinations, experimental or investigative treatment determinations, formulary designs for prescription drugs, network tier design for multiple tier networks, standards for provider admission to participate in a network (including reimbursement rates), step-therapy programs, and restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits. See 45 C.F.R. § 146.136(c)(4).

Issuers should be aware that final 45 C.F.R. Part 146 eliminated the exception that was in the interim final rule that allowed issuers to impose more stringent NQTLs on MH/SUD benefits than on

medical/surgical benefits where "recognized clinically appropriate standards of care" permitted a difference. However, final 45 C.F.R. Part 146 also recognizes that disparate results between allowable limits on the two types of benefits do not, without more, mean that the NQTLs are violating the requirements of the rule.

Although final 45 C.F.R. Part 146 provides numerous examples that demonstrate compliance and noncompliance with the NQTL requirements, one example in particular is noteworthy. Example 10, which is set forth in 45 C.F.R. § 146.136(c)(4)(iii), makes clear that an issuer may not limit coverage for MH/SUD conditions to providers and/or facilities licensed in New York if the issuer does not similarly limit coverage for medical/surgical conditions.

5. Multi-Tiered Prescription Drug Benefits

An insurer may provide multi-tiered prescription drug benefits if they are based on reasonable factors and are without regard to whether a drug is prescribed with respect to medical/surgical benefits or MH/SUD benefits. See 45 C.F.R. § 146.136(c)(3)(iii)(A).

6. Disclosure Requirements

45 C.F.R. § 146.136(d) requires that: (1) the criteria used for medical necessity determinations for MH/SUD benefits be made available to any current or potential participant, beneficiary, or contracting provider upon request; and (2) the reason for any denial of reimbursement or payment for MH/SUD services be made available to the participant or beneficiary.

7. Provider Reimbursement

45 C.F.R. Part 146 clarifies that issuers may consider a wide array of factors in determining provider reimbursement rates for both medical/surgical services and MH/SUD services. These factors include: geographic market; demand for services; supply of providers; provider practice size; Medicare reimbursement rates; and training, experience, and licensure of providers. The NQTL rules require that an issuer apply these factors comparably to and no more stringently than the way that it applies the factors to medical/surgical services. A disparate outcome of applying the factors to the two types of benefits in and of itself does not mean that the issuer has failed to comply with the NQTL requirements. See 45 C.F.R. § 146.136(c)(4)(ii).

8. Intermediate Levels of Care

45 C.F.R. Part 146 addresses coverage for intermediate levels of care such as residential treatment, partial hospitalization, and intensive outpatient treatment. The supplementary information in 45 C.F.R. Part 146 indicates that it neither imposes a benefit mandate for coverage of intermediate levels of care nor permits issuers to exclude intermediate levels of care. Rather, under 45 C.F.R. Part 146, an issuer must assign the intermediate levels of care to the existing benefit classifications in the same way that it assigns comparable intermediate medical/surgical benefits to these classifications. The supplementary information in 45 C.F.R. § 146.136 gives the following examples: "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 mental health or substance use disorders as an inpatient benefit. In addition, if a plan or issuer treats home health care as

an outpatient benefit, than any covered intensive outpatient mental health or substance use disorder services and partial hospitalization must be considered outpatient benefits as well."

Once the proper classification is made, an issuer may only impose financial requirements, quantitative treatment limitations, and NQTLs on those intermediate levels of MH/SUD care consistent with MHPAEA and 45 C.F.R. Part 146. For example, in New York, skilled nursing facilities for medical/surgical conditions are covered as an inpatient benefit. Thus, issuers should cover residential treatment facilities for MH/SUD conditions as an inpatient benefit. This means that an issuer may impose only financial requirements and quantitative treatment limitations on residential treatment facilities for MH/SUD conditions that are no more restrictive than the predominant financial requirements and treatment limitations applied to substantially all medical/surgical benefits covered by the plan in the inpatient classification. Additionally, issuers are prohibited from imposing NQTLs on residential treatment facilities for MH/SUD conditions unless any processes, strategies, evidentiary standards, or other factors used in applying the limitations are comparable to and no more stringent than the processes, strategies, evidentiary standards, or other factors used in applying the limitations to the medical/surgical benefits in the inpatient classification.

III. Conclusion

The ACA, MHPAEA, and 45 C.F.R. Part 146 have had a significant impact on coverage requirements for MH/SUD benefits. This circular letter endeavors to inform issuers of the requirements under the foregoing, and to assist issuers with complying with them.

Please direct any questions regarding this circular letter to Thomas Fusco, Supervising Insurance Attorney, Health Bureau, New York State Department of Financial Services, Walter J. Mahoney Office Building, 65 Court Street, Room 7, Buffalo, New York 14202, or by e-mail at thomas.fusco@dfs.ny.gov.

Very truly yours,

Lisette Johnson
Bureau Chief, Health Bureau

NEW YORK STATE
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Superintendent

Insurance Circular Letter No. 6 (2015)
March 30, 2015

TO: **All Insurers Authorized to Write Accident and Health Insurance in New York State, Article 43 Corporations, Health Maintenance Organizations, Student Health Plans Certified Pursuant to Insurance Law § 1124, and Municipal Cooperatives (collectively, "insurers")**

RE: **Changes in Utilization Review Standards for Substance Use Disorder Treatment Pursuant to Chapter 41 of the Laws of 2014**

STATUTORY REFERENCES: N.Y. Insurance Law Article 49; N.Y. Public Health Law Article 49

Introduction

The purpose of this circular letter is to provide guidance to insurers regarding the changes that Chapter 41 of the Laws of 2014 ("Chapter 41") has made to the utilization review ("UR") provisions in Articles 49 of the Insurance Law and Public Health Law ("Articles 49") relating to substance use disorder ("SUD") treatment and to remind insurers of other statutory requirements regarding availability of clinical review criteria.

Background

Chapter 41 was enacted as part of a package of legislation intended to combat the rise in heroin use in New York. In part, Chapter 41 codified existing requirements regarding health insurance coverage for SUD treatment that resulted from the federal Mental Health Parity and Addiction Equity Act[1]. Additionally, Chapter 41 made changes to a number of provisions in Articles 49 that govern UR in the context of treatment for SUD. These provisions take effect on April 1, 2015 and apply to policies and contracts issued, renewed, modified, altered, or amended on or after that date.

[1] See Insurance Circular Letter No. 5 (2014).

Analysis

A. Definition of "Clinical Peer Reviewer"

Articles 49 defines "clinical peer reviewer" for purposes of utilization review determinations as either a physician who possesses a current and valid non-restricted license to practice medicine or another health care professional who, where applicable: (1) possesses a current and valid non-restricted license, certificate, or registration or, where no provision for a license, certificate, or registration exists, is credentialed by the national accrediting body appropriate to the profession; and (2) is in the same profession and same or similar specialty as the health care provider who typically manages the medical condition or disease or provides the health care service or treatment under review.

Chapter 41 amended the definition of "clinical peer reviewer" by adding a requirement that, for purposes of UR determinations involving SUD treatment, a "clinical peer reviewer" must be either: (1) a currently licensed physician who specializes in behavioral health and has experience in the delivery of SUD courses of treatment; or (2) a health care professional, other than a licensed physician, who specializes in behavioral health, has experience in the delivery of SUD courses of treatment, and is licensed, certified, or registered, where applicable, or if no license, certification, or registration requirement exists, is credentialed by the national accrediting body appropriate to the profession.[2]

The change to the definition of "clinical peer reviewer" applies to Title I of Articles 49, which governs internal UR determinations. The definition of "clinical peer reviewer" for purposes of Title II of Articles 49, which governs external appeals, remains unchanged.

B. UR Criteria

Chapter 41 added a new provision to the UR program standards section in Articles 49. The new provision sets forth standards a UR agent must consider when deciding what criteria to use to determine health care coverage for SUD treatment. It requires that a UR agent who is reviewing SUD treatment for purposes of health insurance coverage must use recognized evidence-based and peer-reviewed clinical review criteria that are appropriate to the age of the patient and are deemed appropriate and approved for such use by the Commissioner of the Office of Alcoholism and Substance Abuse Services ("OASAS") in consultation with the Commissioner of Health and the Superintendent of Financial Services ("Superintendent").[3]

OASAS strongly encourages UR agents to use the Level of Care for Alcohol and Drug Treatment Referral ("LOCADTR") tool to determine health care coverage for SUD treatment. LOCADTR is a web-based patient placement criteria system designed for use in making level of care decisions in New York State. As described on the OASAS website, a level of care determination is a clinical procedure provided by OASAS-certified alcoholism and substance abuse treatment services

[2] Insurance Law § 4900(b)(1)(B)(ii)(C); Public Health Law § 4900.2(a)(i)(B).

[3] Insurance Law § 4902(a)(9); Public Health Law § 4902.1(i).

or by qualified health professionals, as defined in the OASAS chemical dependence regulations. See http://www.oasas.ny.gov/treatment/health/locadtr/index.cfm. As such, LOCADTR is pre-approved by OASAS for use in SUD treatment determinations. UR agents who use LOCADTR will only be required to notify the Commissioner of OASAS by letter, with copies of the letter sent to the Commissioner of Health and the Superintendent. It is expected that OASAS will require UR agents to use the LOCADTR tool to determine coverage for SUD treatment provided through NYS Medicaid Managed Care. While LOCADTR should be used by UR agents to determine level of care, coverage will depend on the terms of the individual's insurance contract or policy.

A UR agent who does not use LOCADTR must submit to OASAS the UR criteria that the UR agent intends to use no later than 60 days before the date that the criteria are intended to be used. The UR agent must demonstrate to OASAS that the criteria are recognized as evidence-based and peer-reviewed and that the criteria are appropriate to the age of the patients to whom they are intended to apply. The criteria may not be used until OASAS deems them appropriate and approves their use. Notice of such approval should be forwarded to the Commissioner of Health and the Superintendent.

C. Request for Inpatient SUD Treatment

Articles 49 provides that a UR agent must make a determination involving continued or extended health care services and provide notice of the determination within one business day of the receipt of the necessary information except, with respect to home health care services following an inpatient hospital admission, within 72 hours of receipt of all of the necessary information when the day subsequent to the request falls on a weekend or holiday. Chapter 41 amended Articles 49 by adding a requirement that a UR agent must make a determination regarding a request for inpatient SUD treatment within 24 hours of receiving the request, if the request is submitted to the UR agent at least 24 hours before discharge from an inpatient admission. Further, if the request for inpatient SUD treatment is submitted to the UR agent at least 24 hours before discharge from an inpatient admission, the UR agent may not deny, on the basis of medical necessity or lack of prior authorization, coverage for the inpatient SUD treatment while the UR agent's determination is pending.[4]

D. Expedited Appeal of Inpatient SUD Treatment

Articles 49 provides that when an appeal is expedited, a UR agent must make a determination on an adverse determination within two business days of receiving information necessary to conduct the appeal. Chapter 41 amended Articles 49 to require a UR agent to determine an expedited appeal of an adverse determination of a request for inpatient SUD treatment within 24 hours of receiving the appeal if the initial request for inpatient SUD treatment was submitted at least 24 hours before discharge from an inpatient admission. If an insured or an insured's provider files an expedited internal and external appeal within 24 hours from receiving an adverse determination for inpatient SUD treatment for which coverage was provided while the initial utilization review determination was pending pursuant to Insurance Law § 4903(c)(3) or Public Health Law § 4903.3(c), a UR agent may not deny on the basis of medical necessity or lack of prior authorization coverage of the inpatient SUD treatment while a determination by the UR agent or external appeal agent is pending.[5] In the

[4] Insurance Law § 4903(c); Public Health Law § 4903.3.

[5] Insurance Law § 4904(b); Public Health Law § 4904.2.

event the external appeal agent upholds the adverse determination, the UR agent may deny coverage of the services only prospectively from the date of the external appeal agent's determination.

E. Availability of Clinical Review Criteria

Section 4903(e)(3) of the Insurance Law and § 4903(5)(c) of the Public Health Law require that a UR agent who makes an adverse determination must, in its notice of adverse determination, notify the insured or the insured's designee of the availability upon request of the clinical review criteria relied upon to make the determination. Additionally, §§ 3217-a(b)(10) and 4324(b)(10) of the Insurance Law and § 4408(2)(j) of the Public Health Law require that, upon written request, an insurer must provide specific written clinical review criteria relating to a particular condition or disease to an insured or prospective insured.

Conclusion

Chapter 41 amends Articles 49 in several ways as they relate to SUD treatment. It modifies the definition of clinical peer reviewer, sets forth standards for determining the UR criteria to be used, shortens the timeframes for a UR agent to make an initial or expedited appeal determination regarding a request for inpatient SUD treatment and to provide notice of the determination, and prohibits, under certain circumstances, a UR agent from denying on the basis of medical necessity or lack of prior authorization coverage for inpatient SUD treatment while either an initial determination, expedited appeal, or external appeal is pending.

Please direct any questions regarding this circular letter to Thomas Fusco, Supervising Insurance Attorney, by mail at Health Bureau, New York State Department of Financial Services, Walter J. Mahoney Office Building, 65 Court Street, Room 7, Buffalo, New York 14202, or by e-mail at thomas.fusco@dfs.ny.gov.

Very truly yours,

Lisette Johnson
Bureau Chief, Health Bureau

NEW YORK STATE
DEPARTMENT of FINANCIAL SERVICES

Andrew M. Cuomo
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Maria T. Vullo
Superintendent

Insurance Circular Letter No. 4 (2016)
July 27, 2016

TO: **All Insurers Authorized to Write Accident and Health Insurance in New York State, Article 43 Corporations, Health Maintenance Organizations, Student Health Plans Certified Pursuant to Insurance Law § 1124, and Municipal Cooperative Health Benefit Plans (collectively, "issuers")**

RE: **United States Department of Labor and United States Department of Health and Human Services Compliance Guidance "Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance"**

STATUTORY AND REGULATORY REFERENCES: 42 U.S.C. § 300gg-1, et seq.; 42 U.S.C. § 18001, et seq.; 29 U.S.C. § 1185a; 45 C.F.R. Parts 146 and 147; and N.Y. Ins. Law §§ 3103, 3201, 3221, 4303, and 4308

The purpose of this circular letter is to inform insurers authorized to write accident and health insurance in New York State, Article 43 corporations, health maintenance organizations, student health plans certified pursuant to Insurance Law § 1124, and municipal cooperative health benefit plans (collectively, "issuers") of recent guidelines for mental health treatment.

Issuers are reminded of DFS Circular Letter Number 1 (2016), which informed health insurance issuers of their obligations to cover mental health and substance use disorder ("MH/SUD") services in accordance with federal and state law. Recently, the United States Department of Labor ("DOL") and the United States Department of Health and Human Services ("HHS") issued guidance[1] that provides examples of non-quantitative treatment limitations ("NQTLs") for MH/SUD benefits that may violate the federal Mental Health Parity and Addiction Equity Act ("MHPAEA") codified in 29 U.S.C. § 1185a. MHPAEA prohibits issuers whose policies or contracts provide medical and surgical benefits and MH/SUD benefits from applying financial requirements, quantitative treatment limitations ("QTLs"), and NQTLs to MH/SUD benefits that are more restrictive than the predominant financial requirements or treatment limitations that are applied to substantially all medical and surgical benefits covered by the plan.

[1] The DOL/HHS guidance is available on the DOL website at https://www.dol.gov/ebsa/pdf/warning-signs-plan-or-policy-nqtls-that-require-additional-analysis-to-determine-mhpaea-compliance.pdf and on the HHS website at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/MHAPEAChecklistWarningSigns.pdf.

The Department advises issuers that they may not impose a NQTL on MH/SUD benefits unless the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefits in a classification (inpatient in-network, inpatient out-of-network, outpatient in-network, outpatient out-of-network, prescription drugs and emergency care) are applied no more stringently than those used in applying the limitation with respect to medical and surgical benefits in the same classification. [2]

Furthermore, according to the DOL/HHS guidance, absent similar restrictions on the medical and surgical benefits, the following policy or contract provisions may serve as a warning that an issuer may be imposing an impermissible NQTL. DOL/HHS has recommended that state regulators further review the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to both MH/SUD and medical and surgical benefits to determine parity compliance:

- preauthorization and pre-service notice requirements;
- fail-first protocols;
- probability of improvement requirements;
- written treatment plan requirement; and
- other requirements, such as patient non-compliance rules, residential treatment limits, geographical limitations, and licensure requirements.

Accordingly, issuers are advised that the Department of Financial Services will be reviewing issuers' NQTLs and QTLs to ensure that issuers fully comply with MHPAEA and will take necessary action in the event of any non-compliance.

Please direct any questions regarding this circular letter to Thomas Fusco, Supervising Insurance Attorney, Health Bureau, New York State Department of Financial Services, Walter J. Mahoney Office Building, 65 Court Street, Room 7, Buffalo, New York 14202 or by e-mail at Thomas.Fusco@dfs.ny.gov.

Very truly yours,

Lisette Johnson
Bureau Chief, Health Bureau

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[2] QTLs are treatment limitations that are numerical in nature and include annual or lifetime day and visit limits. NQTLs are limits on the scope and duration of treatment that are not numerical in nature. NQTLs include medical management standards, medical necessity determinations, experimental or investigative treatment determinations, formulary designs for prescription drugs, network tier design for multiple tier networks, standards for provider admission to participate in a network, provider reimbursement rates, step-therapy programs, and restrictions based on geographic location, facility type, and provider specialty.

NEW YORK STATE
DEPARTMENT *of*
FINANCIAL SERVICES

Andrew M. Cuomo
Governor

Maria T. Vullo
Superintendent

Insurance Circular Letter No. 6 (2016)
October 19, 2016

TO: **All Insurers Authorized to Write Accident and Health Insurance in New York State, Article 43 Corporations, Health Maintenance Organizations ("HMOs"), Student Health Plans Certified Pursuant to Insurance Law § 1124, and Municipal Cooperative Health Benefit Plans**

RE: Coverage for Substance Use Disorder Treatment

STATUTORY AND REGULATORY REFERENCES: N.Y. Ins. Law §§ 3201, 3216, 3221, 4303, 4308, 4902, and Article 49; N.Y. Pub. Health Law Article 49; 11 NYCRR § 52.16(c); 29 U.S.C. § 1185a; 42 U.S.C. § 300gg-1 et seq.; 42 U.S.C. § 18001 et seq.; 45 C.F.R. Parts 146 and 147; 45 C.F.R. § 156.122; 29 C.F.R § 2560.503-1; 29 C.F.R § 2590.715-2719

I. Purpose

Against the backdrop of the opioid epidemic, which has had a devastating impact in New York, this circular letter provides direction to insurers authorized to write accident and health insurance in this state, article 43 corporations, health maintenance organizations, student health plans certified pursuant to Insurance Law § 1124, and municipal cooperative health benefit plans (collectively, "issuers") regarding the coverage requirements for treatment of substance use disorders under insurance policies or contracts delivered or issued for delivery in New York. The letter addresses both existing protections in the Insurance Law and regulations thereunder for coverage of substance use disorder treatment, as well as a number of new protections recently enacted into law pursuant to Chapters 69 and 71 of the Laws of 2016.

The letter also serves as reminder to issuers that strict compliance with all existing statutory and regulatory requirements for coverage of substance use disorder treatment is critical. This circular letter supplements Insurance Circular Letters No. 15 (2002), No. 5 (2014), No. 6 (2015), and No. 4 (2016).

II. Chapter 69 of the Laws of 2016 ("Chapter 69")

A. Clinical Review Tool for Utilization Review of Substance Use Disorder Treatment

Currently, Insurance Law § 4902(a)(9) and Public Health Law § 4902(1)(j) require issuers and their agents that conduct utilization review ("utilization review agents") for substance use disorder treatment to use recognized evidence-based and peer reviewed clinical review criteria that

is appropriate to the age of the patient and is deemed appropriate and approved for use by the Commissioner of the Office of Alcoholism and Substance Abuse Services ("OASAS"), in consultation with the Commissioner of Health and the Superintendent of Financial Services. Chapter 69 amended those sections to require that issuers and their utilization review agents use evidence-based and peer reviewed clinical review tools designated by OASAS that are appropriate to the age of the patient and consistent with the treatment service levels within the OASAS system. Chapter 69 further requires all approved tools to have inter-rater reliability testing completed by December 31, 2016. Issuers and utilization review agents must update their processes to reflect the new requirements with respect to health insurance policies or contracts issued, renewed, modified, altered or amended on or after January 1, 2017.

B. Prescription Drug Coverage for Substance Use Disorder

Under current law, large group health insurance policies or contracts[1] are not required to cover prescription drugs. Chapter 69 added new Insurance Law §§ 3221(l)(7-a) and 4303(l-1) to require every large group policy or contract that provides medical, major medical or similar comprehensive-type coverage to provide coverage for medication approved by the U.S. Food and Drug Administration ("FDA") for the detoxification or maintenance treatment of a substance use disorder. An issuer must include the new coverage in its large group policies or contracts that are issued, renewed, modified, altered or amended on or after January 1, 2017. Accordingly, issuers must amend any large group policy or contract that provides medical, major medical or similar comprehensive-type coverage but does not include coverage for medication approved by the FDA for the detoxification or maintenance treatment of a substance use disorder. Large group health insurance policies and contracts that currently cover prescription drugs should already be covering medication approved by the FDA for the detoxification or maintenance treatment of a substance use disorder.

Chapter 69 also added new Insurance Law §§ 3216(i)(31-a), 3221(l)(7-b), and 4303(l-2) to require every policy or contract that provides medical, major medical or similar comprehensive-type coverage and provides coverage for prescription drugs for the treatment of a substance use disorder to include immediate access, without prior authorization, to a five-day emergency supply of prescribed medications otherwise covered under the policy or contract for the treatment of a substance use disorder where an emergency condition exists, including a prescribed drug or medication associated with the management of opioid withdrawal or stabilization, except where otherwise prohibited by law. Coverage of an emergency supply includes medication for opioid overdose reversal otherwise covered under the policy or contract when prescribed to an individual covered under the policy or contract.

Insurance Law §§ 3216(i)(31-a), 3221(l)(7-b), and 4303(l-2) further provide that coverage of the five-day emergency supply of medication may be subject to copayments, coinsurance, and annual deductibles that are consistent with those imposed on other benefits within the policy or contract, and prohibit issuers from imposing an additional copayment or coinsurance on an insured who received an emergency supply of medication and then received up to a 30-day supply of the same medication in the same 30-day period in which the emergency supply of medication was dispensed. However, issuers may impose a copayment or coinsurance on the initial emergency

[1] A large group health insurance policy or contract is one which covers more than 100 employees or members of the group, exclusive of spouses and dependents. See Insurance Law §§ 3231(a)(1) and 4317(a)(1).

supply of medication in an amount that is less than the copayment or coinsurance otherwise applicable to a 30-day supply of the medication, provided that the total sum of the copayments or coinsurance for an entire 30-day supply of the medication does not exceed the copayment or coinsurance otherwise applicable to a 30-day supply of the medication. These new five day emergency supply requirements apply to policies or contracts issued, renewed, modified, altered, or amended on or after January 1, 2017. The Department of Financial Services ("Department") will provide model contract language to assist issuers with compliance.

III. Chapter 71 of the Laws of 2016 ("Chapter 71")

A. Coverage in Residential Settings

Insurance Law §§ 3216(i)(30), 3221(l)(6) and 4303(k) currently require every policy or contract that provides hospital, major medical or similar comprehensive coverage to include inpatient coverage for the diagnosis and treatment of substance use disorder, including detoxification and rehabilitation services. Chapter 71 amended those sections to clarify that inpatient coverage includes unlimited medically necessary treatment for substance use disorder treatment services provided in a residential setting as required by the federal Mental Health Parity and Addiction Equity Act of 2008, codified at 29 U.S.C. § 1185a ("MHPAEA"). Notwithstanding this statutory clarification, in order to comply with MHPAEA, issuers currently should be covering services in residential treatment facilities for mental health or substance use disorder ("MH/SUD") if intermediate levels of care are covered under the medical and surgical benefits of their policies and contracts. The Department's model contract language specifically includes language addressing coverage of services provided in residential settings. Issuers that utilize the Department's model contract language currently are in compliance with the requirement for coverage of residential treatment. Issuers that have approved policies or contracts that do not use the model contract language and do not include a specific reference to coverage in residential settings must revise their policies or contacts upon issuance or renewal.

B. Prohibition against Preauthorization and Concurrent Review During First 14 Days of Inpatient Admission for Treatment of Substance Use Disorder

Chapter 71 also added new Insurance Law §§ 3216(i)(30)(D), 3221(l)(6)(D), and 4303(k)(4), which apply to New York facilities that are certified by OASAS and participate in the issuer's provider network. These new provisions prohibit issuers from requiring preauthorization. These provisions further prohibit issuers from performing concurrent utilization review during the first 14 days of the inpatient admission provided the facility notifies the issuer of both the admission and the initial treatment plan within 48 hours of the admission. If the facility does not notify the issuer of both the admission and the initial treatment plan within 48 hours of the admission, then the issuer may perform concurrent utilization review immediately.

In addition, these sections require the facility to perform daily clinical review of the patient, including periodic consultation with the issuer, to ensure that the facility is using the evidence-based and peer-reviewed clinical review tool utilized by the issuer that is designated by OASAS and appropriate to the patient's age in order to guarantee that the inpatient treatment is medically necessary for the patient. An issuer's utilization review of the inpatient treatment may commence after the 14th day of the inpatient admission and may include a review of all services provided during the first 14 days of the inpatient treatment. However, an issuer may deny coverage for any

portion of the initial 14-day inpatient treatment on the basis that the treatment was not medically necessary only if the inpatient treatment was contrary to the evidence-based and peer-reviewed clinical review tool utilized by the issuer and designated by OASAS. An insured shall not have any financial obligation to the facility for the inpatient treatment other than any copayment, coinsurance, or deductible otherwise required under the policy or contract.

An issuer must include these new requirements in policies or contracts that are issued, renewed, modified, altered or amended on or after January 1, 2017. The Department will provide model contract language to assist issuers with compliance.

C. Copayments and Coinsurance for Limited Initial Prescription of an Opioid Drug

Chapter 71 also added a new Public Health Law § 3331.5(b), which prohibits a practitioner from prescribing more than a seven-day supply of any schedule II, III, or IV opioid to an ultimate user upon the initial consultation or treatment of the user for "acute pain" as defined in § 3331.5(c). It permits the practitioner to issue any appropriate renewal, refill, or new prescription for the opioid or any other drug for the same pain upon subsequent consultations. At the same time, Chapter 71 also added new Insurance Law §§ 3216(i)(33), 3221(k)(21) and 4303(qq), which require a policy or contract providing prescription drug coverage subject to a copayment to charge a copayment for a limited initial prescription of an opioid drug that is either: (1) proportional between the copayment for a 30-day supply and the amount of drugs the patient was prescribed; or (2) equivalent to the copayment for a full 30-day supply of the opioid drug, provided that no additional copayments may be charged for any additional prescriptions for the remainder of the 30-day supply.

This new requirement is effective as of July 22, 2016. Issuers should administer their policy and contract forms in accordance with this requirement pending submission and approval of amended policy and contract forms.

D. Financial Requirements and Treatment Limitations for Substance Use Disorder Treatment

Insurance Law §§ 3216(i)(30), 3216(i)(31), 3221(l)(6)(A), 3221(l)(7)(A), 4303(k)(1), and 4303(l)(1) expressly state that inpatient and outpatient coverage may not apply financial requirements or treatment limitations to substance use disorder benefits that are more restrictive than the predominant financial requirements and treatment limitations applied to substantially all medical and surgical benefits covered by the insurance policy or contract. These sections further state that the coverage must be provided consistent with MHPAEA. Chapter 71 amended Insurance Law §§ 3216(i)(30), 3221(l)(6)(A), and 4303(k)(1) to include a reference to parity for utilization review requirements, consistent with MHPAEA.

MHPAEA prohibits issuers providing medical and surgical benefits and MH/SUD benefits from applying financial requirements or quantitative and non-quantitative treatment limitations ("QTLs" and "NQTLs") to MH/SUD benefits that are more restrictive than the predominant financial requirements or treatment limitations that are applied to substantially all medical and

surgical benefits covered by the policy or contract.[2] Insurance Circular Letter No. 5 (2014) and Insurance Circular Letter No. 4 (2016) provide guidance to issuers about MHPAEA requirements.

IV. Financial Requirements and Treatment Limitations for Prescription Drugs

When determining whether a financial requirement or treatment limitation applied to a MH/SUD benefit is in compliance with MHPAEA, an issuer should categorize the benefit in one of six classifications: inpatient in-network; inpatient out-of-network; outpatient in-network; outpatient out-of-network; emergency care; and prescription drugs. See 45 C.F.R. § 146.136(c)(1)(i). For a financial requirement or treatment limitation on prescription drug coverage for MH/SUD to be permissible, it may be no more restrictive than the predominant financial requirements or treatment limitations applied to substantially all prescription drugs used to treat medical or surgical conditions. In the context of prescription drug coverage, multi-tiering is a common financial requirement. MHPAEA recognizes that some health insurance policies include multi-tiered prescription drug coverage. Under 45 C.F.R. § 146.136(c)(3)(iii)(A), multi-tiering does not violate MHPAEA if the different levels of financial requirements for different prescription drug tiers are based on reasonable factors and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to MH/SUD benefits. Under 45 C.F.R. § 146.136(c)(3)(iii)(A), reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up. Issuers implementing a multi-tier prescription drug benefit must ensure that the tier placement of a particular drug or drugs used to treat MH/SUD is based on reasonable factors and without regard to whether the drug or drugs are generally prescribed to treat MH/SUD.

Pursuant to 45 C.F.R. § 146.136(c)(4)(i), issuers may not impose NQTLs with respect to MH/SUD in any classification unless any processes, strategies, evidentiary standards, or other factors used in applying the limitations are comparable to and no more stringent than the processes, strategies, evidentiary standards, or other factors used in applying the limitations to the medical/surgical benefits in the classification.

In accordance with 45 C.F.R. § 146.136(c)(4)(ii), NQTLs relative to prescription drugs include formulary design and medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative. An issuer that requires an insured to seek and obtain prior approval for a prescription drug to treat MH/SUD must ensure that the processes, strategies, evidentiary standards or any other factor used in determining that a prescription drug for MH/SUD requires prior approval are comparable to and no more stringent than those used in determining whether a prescription drug for a medical/surgical condition requires prior approval.

Similarly, when an issuer develops its formulary and determines which MH/SUD drugs will be included on the formulary, it must use processes, strategies, evidentiary standards or other factors that are comparable and no more stringent than the processes, strategies, evidentiary standards, or other factors that it uses in determining what medical/surgical prescription drug are included in its formulary.

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[2] QTLs are treatment limitations that are numerical in nature and include annual or lifetime day and visit limits. NQTLS are limits on the scope and duration of treatment that are not numerical in nature and include utilization review requirements.

V. Existing Coverage Requirements for Outpatient Substance Use Disorder Treatment

Insurance Law §§ 3216(i)(31), 3221(l)(7) and 4303(l), and 45 C.F.R. § 146.136 require every policy or contract that provides medical, major medical, or similar comprehensive-type coverage to provide outpatient coverage for the diagnosis and treatment of substance use disorder, which includes detoxification and rehabilitation services. Under these sections, coverage may be limited to facilities in New York State certified by OASAS or licensed by OASAS as outpatient clinics or medically supervised ambulatory substance use programs and, in other states, to those facilities that are accredited by the Joint Commission as alcoholism or chemical dependence substance abuse treatment programs or, pursuant to MHPAEA, those facilities licensed or certified by a state agency similar to OASAS. Outpatient coverage also includes partial hospitalization services and services provided in a professional office setting because those services are in the outpatient benefit classification for purposes of MHPAEA. In order to be compliant with MHPAEA, if outpatient services are covered under the medical and surgical benefits, then partial hospitalization services and services provided in a professional office setting for MH/SUD must be covered in parity with medical and surgical benefits in that same classification.

VI. Coverage of Naloxone

According to the federal Substance Abuse and Mental Health Services Administration's website, naloxone is an FDA-approved prescription drug used to block or prevent the effects of opiates and opioids, such as heroin and oxycodone.[3] It is often used in an emergency situation to prevent or reverse the effects of an opioid overdose.

It has been brought to the Department's attention that some issuers currently may not be providing health insurance coverage for naloxone when provided on an outpatient basis. Under the federal Affordable Care Act ("ACA"), individual and small group health insurance policies or contracts must provide a comprehensive package of items and services, which are known as essential health benefits ("EHB"). Prescription drugs are specifically identified as an EHB that must be covered. Pursuant to 45 C.F.R. § 156.122(a)(1), a health insurance policy or contract providing coverage in the individual or small group market would not be considered to be providing EHB unless, in relevant part, it covers at least the greater of at least one drug in every United States Pharmacopeia category and class or the same number of prescription drugs in each category and class as the EHB-benchmark plan. With respect to large groups, issuers must provide coverage for medication approved by the FDA for the detoxification or maintenance treatment of a substance use disorder in all policies and contracts issued, renewed, modified, altered or amended on or after January 1, 2017. However, because MHPAEA requires policies and contracts that currently cover prescription drugs to also cover prescription drugs to treat substance use disorder on parity with prescription drugs to treat medical conditions, all current large group policies and contracts that provide prescription drug coverage must currently provide coverage for substance use disorder medication on parity with other prescription drugs.

Furthermore, § 52.16(c) of 11 NYCRR 52 (Insurance Regulation 62) prohibits issuers offering individual, small group and large group health insurance policies from limiting or excluding coverage by type of illness, accident, treatment, or medical condition. In order to

[3] See http://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone.

comply with these requirements, issuers should provide coverage for naloxone on an outpatient basis when prescribed to insureds by authorized providers, as they would for any other prescribed drug, subject to the terms and conditions of the health insurance policy or contract. In addition, naloxone also should be covered on an inpatient basis when medically necessary.

VII. Utilization Review

Insurance Law and Public Health Law Articles 49 and regulations promulgated thereunder, 42 U.S.C. § 18001 et seq. and its implementing regulations, and 29 C.F.R. § 2560.503-1 establish utilization review requirements, including timeframes in which utilization review determinations must be made. As explained in Insurance Circular Letter No. 15 (2002), issuers and their utilization review agents are responsible for complying with both state and federal utilization review requirements. In instances when the state and federal requirements and timeframes are not identical, the stricter requirement or the shorter decision timeframe applies. Therefore, the guidance set forth below combines the requirements from the foregoing laws and regulations to apply the standard that is more favorable to the insured.

A. Initial Preauthorization Adverse Determinations

Issuers and utilization review agents must make preauthorization decisions within prescribed timeframes that must be shortened for a "claim involving urgent care." A "claim involving urgent care" is defined by 29 C.F.R. § 2560.503-1(m)(1) as any claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations: (1) could seriously jeopardize the life or health of the insured or the ability of the insured to regain maximum function; or (2) in the opinion of a physician with knowledge of the insured's medical condition, would subject the insured to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim.

Issuers and utilization review agents must make urgent preauthorization determinations and provide notice to the insured or the insured's designee and the insured's provider within 72 hours of receipt if the request is complete when submitted, with written notice to follow within three business days of receipt of the request. If the request is incomplete, issuers and utilization review agents must request any additional information within 24 hours. The insured, the insured's designee, and the insured's provider must be given 48 hours to submit the information. Issuers and utilization review agents must make a decision and provide notice to the insured or the insured's designee and the insured's provider within 48 hours of the earlier of the receipt of the information or the end of the 48-hour period. Written notification must follow within the earlier of three business days of receipt of the information or three calendar days after the verbal notification.

Additionally, under Insurance Law § 4903(c) and Public Health Law § 4903(3), if a request for inpatient substance use disorder treatment is made at least 24 hours prior to discharge from an inpatient substance use disorder treatment admission, then issuers and utilization review agents must make a decision within 24 hours of receipt of the request and provide coverage for the inpatient substance use disorder treatment while the determination is pending. See also Insurance Circular Letter No. 6 (2015).

Issuers and utilization review agents must make non-urgent preauthorization decisions within three business days of receipt if the request is complete when submitted. If the request is incomplete, issuers and utilization review agents must request any additional information within three business days. Issuers and utilization review agents must give the insured, the insured's designee, and the insured's provider 45 calendar days to submit the information. Issuers and utilization review agents must make a decision within three business days of receipt of the information or within 15 calendar days of the end of the 45 day period if the information is not received. Notice of the determination must be provided to the insured or the insured's designee and the insured's provider by telephone and in writing.

B. Preauthorization Internal Appeals

Issuers and utilization review agents must make expedited appeal decisions within the earlier of 72 hours of receipt of the appeal or two business days of receipt of the necessary information to conduct the appeal.

Additionally, if an issuer or utilization review agent denies a request for inpatient substance use disorder treatment that was submitted at least 24 hours prior to discharge from an inpatient substance use disorder treatment admission, and the insured or the insured's provider files an expedited appeal, a decision must be made within 24 hours of receipt of the appeal and coverage must be provided for the inpatient substance use disorder treatment while the appeal is pending. See also Insurance Circular Letter No. 6 (2015).

Under 29 C.F.R. § 2560.503-1(i)(2)(ii), issuers and utilization review agents must make non-expedited preauthorization appeal decisions within 30 days from receipt of the appeal if the issuer or utilization review agent has one level of internal appeal, or 15 days from receipt of the appeal if the issuer or utilization review agent has two levels of appeal.

C. Formulary Exception Process

Individual and small group health insurance policies or contracts must have a standard and expedited formulary exception process for an insured or an insured's designee and the insured's prescribing health care professional to request a clinically-appropriate prescription drug that is not otherwise covered by the issuer. An issuer must make a determination and notify the insured or the insured's designee and the prescribing health care professional no later than 72 hours after receipt of a standard formulary exception request and no later than 24 hours after receipt of an expedited formulary exception request. If coverage is denied under either a standard or expedited formulary exception request, then the insured is entitled to an external appeal in accordance with Articles 49 of the Insurance Law or Public Health Law.

D. External Appeals

Pursuant to Title II of Articles 49 of the Insurance Law and Public Health Law, 11 NYCRR 410, and 45 C.F.R. § 147.136, an insured who receives a denial for preauthorization of health care services or a denial of a formulary exception request, including substance use disorder treatment, must be provided a right to an independent external appeal. External appeal rights must be provided after the first level of internal appeal and the insured may not be required to obtain a

second level of internal appeal with the issuer or utilization review agent in order to be eligible for an external appeal.

VIII. Conclusion

The Department intends to investigate issuers' compliance with requirements for coverage of substance use disorder treatment as described in this circular letter, including during market conduct exams. The Department will take action against an issuer for any failure to adhere to all statutory and regulatory requirements for substance use disorder treatment.

Please direct any questions regarding this circular letter to Thomas Fusco, Supervising Insurance Attorney, Health Bureau, New York State Department of Financial Services, Walter J. Mahoney Office Building, 65 Court Street, Room 7, Buffalo, New York 14202 or by e-mail at Thomas.Fusco@dfs.ny.gov.

Very truly yours,

Lisette Johnson
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