



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<sup>1</sup> 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

---

<sup>1</sup> 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 contracts 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.<sup>2</sup> 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.

---

<sup>2</sup> 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(1)(7) and 4303(1), 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.<sup>3</sup> 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

---

<sup>3</sup> 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](mailto:Thomas.Fusco@dfs.ny.gov).

Very truly yours,

Lisette Johnson  
Bureau Chief, Health Bureau