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August 29, 2016

Cecilia Muñoz

Director, Domestic Policy Council

The White House

1600 Pennsylvania Ave, NW

Washington, DC 20500

Dear Ms. Muñoz,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 4,000 physicians and allied health professionals who specialize in the treatment of addiction, I write to applaud the President for establishing the Mental Health and Substance Use Disorder Parity Task Force and to thank the Administration for its work to ensure equal coverage of and meaningful access to mental health and substance use disorder (MH/SUD) treatment. Thorough implementation and strong enforcement of the Mental Health Parity and Addiction Equity Act (MHPAEA) and the Affordable Care Act's (ACA) parity provisions are essential to ensuring the tens of millions of Americans suffering from these diseases can access the care they need. We offer the comments below based on our members' collective experience providing treatment services to patients with addiction and hope they will inform the Task Force's recommendations due in October 2016.

Task Force Goal 1: Promote compliance with parity best practices

Unfortunately, since the parity law was enacted in 2008, there has continued to be non-compliance with the law, and most states are not actively enforcing the law. People in need of MH/ SUD care continue to face significant problems in accessing effective, evidence-based services and medications. When MH/SUD services and medications are covered by plans, it is often difficult to access the clinically appropriate type, amount, and duration of care. These coverage and access problems continue to be more onerous for people with MH/SUD care needs than for people with other chronic health conditions. Common types of parity non-compliance include:

- 1. Disclosure.** There is a lack of disclosure by plans on the development and application of non-quantitative treatment limitations (NQTLs). Transparency is essential to ensure that plan participants and beneficiaries receive medically necessary health care coverage and access to treatment based on parity-compliant benefit plan design, medical management protocols, and other NQTLs. Therefore, proper disclosure of information is especially important to plan participants and beneficiaries seeking mental health/substance use disorder (MH/SUD) treatment and recovery support services and the providers who help them. This is true whether a patient is trying to understand an adverse benefit determination or challenging what appears to be an unlawful NQTL utilized by a health plan, either as written, as applied or both. Parity compliance testing cannot be performed on coverage limitations such as formulary design, medical and administrative management techniques, including restrictions based on facility type or provider specialty, without information about the development and application of these NQTLs.
- 2. Network Adequacy.** Plans generally have fewer providers in their MH/SUD networks than they do in their medical/surgical networks due to several factors including low reimbursement rates, phantom networks and a “narrow network” approach by many plans. Reimbursement for addiction treatment services is especially low, particularly in state Medicaid programs, and prompts many specialists to opt out of insurance networks. However, specialists who are willing to accept low reimbursement rates often find that insurers won’t credential them for addiction treatment services if their primary board certification is not psychiatry. Even though the federal government recognizes certification by the American Board of Addiction Medicine (ABAM), which many non-psychiatrists possess, some insurers still restrict reimbursement for addiction treatment services to psychiatrists. Consequently, a higher percentage of MH/SUD patients are treated by out-of-network providers as compared to medical/surgical patients, leading to higher out-of-pocket spending by MH/SUD patients.

This problem is compounded by the federal limits on the number of patients a qualified and waived practitioner can treat with buprenorphine. A secondary analysis of a plan’s network must be conducted to ascertain whether practitioners are at their buprenorphine patient limit. If every in-network provider is at or close to the patient limit, patients seeking office-based opioid addiction treatment cannot access care and thus the network is not adequate.

- 3. Lack of Parity in Prior Authorization (PA), Concurrent and Retrospective reviews.** Plans generally apply more stringent medical management techniques, both as written and/or as applied in operation, including PA, concurrent and retrospective review requirements, to MH/SUD benefits than to medical/surgical benefits.

One of the most common complaints of ASAM members is non-parity-compliant prior authorization (PA) requirements for addiction medications. Our members

regularly report that high-dosage opioids for the treatment of pain require no PA, but buprenorphine for the treatment of opioid addiction may require PA every 30 days. Moreover, physicians are often required to submit lengthy and clinically unnecessary documentation with their PA request, such that the process becomes time-intensive, expensive and a barrier to needed care. As an example, attached to this letter is one such email from an ASAM member describing two PA processes that can require upwards of 100 pages of documentation for approval. The relevant PA forms from the named insurers are also attached.

As another example, the Utah Department of Health PA form for buprenorphine requires a taper plan be in place before the prescription is approved, contrary to clinical best practices. Further, only 18 months of the medication will be approved. An additional 18 months of treatment may be approved upon a second application, but the Medicaid program will pay for no more than three years of treatment under any circumstances. Such restrictions are not in place for medications to treat other chronic diseases such as diabetes or asthma. The PA form referenced is attached to this letter.

Finally, PA forms often require physicians to document that patients are receiving counseling or other behavioral health services. However, these services are often unavailable as in-network benefits, particularly through state Medicaid programs, due to poor reimbursement, as discussed above.

In response to these non-parity-compliant forms, ASAM has developed a sample PA form that requests medically relevant information for prescribing buprenorphine products. ASAM supports the least restrictive utilization management process and feels that this form is a version that requests only relevant information. A copy of this form is also attached to this letter.

- 4. Dosage/Lifetime Limits and Lack of Coverage for Addiction Medications.** Many commercial insurers and state Medicaid programs continue to limit access to medications for opioid addiction treatment through dosage limitations, lifetime limits, or complete lack of coverage.

Regarding dosage limitations, please see the attached Passport PA form referenced above, which requires monthly approval and a tapering plan for patients on more than 16 mg of buprenorphine, even though the FDA-approved product label goes up to 24 mg and dosing should be at the discretion of the prescriber.

Even though the Final Rule on the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program and Alternative Benefits Plans explicitly notes that a lifetime limit on buprenorphine that does not apply to other prescription drugs violates parity, we know at least one state continues to impose a lifetime limit on buprenorphine in its Medicaid program.

Finally, many state Medicaid programs and commercial insurers exclude coverage for methadone altogether, limiting access to one of only three FDA-approved medications for this disease. For example, an analysis by The National Center on Addiction and Substance Abuse found that seven 2017 EHB-benchmark plans explicitly exclude methadone.ⁱ Such a wholesale exclusion of coverage for an evidence-based treatment option amid an opioid addiction and overdose epidemic should be closely scrutinized and if found to be a parity violation, non-compliant plans should be penalized.

5. **Facility-type/Level of Care Restrictions.** Plans generally impose more restrictive limitations and exclusions on facility-types and clinically recognized levels of care for MH/SUD benefits than are imposed on medical/surgical benefits. Most notably, plans continue to exclude non-hospital based residential treatment and residential levels of care for SUDs and eating disorders.

We are very concerned that violations of MHPAEA will continue absent strong enforcement. We cannot emphasize this enough. ASAM urges the Departments to provide aggressive oversight and enforcement around MHPAEA compliance and provide guidance to states on the same.

Recommendations:

- The Agencies must enforce the regulations, as clarified through additional sub-regulatory guidance on parity disclosure requirements, and impose penalties on non-compliant plans. Guidance should be provided to states regarding enforcement and application of penalties in non-compliant plans. Using concrete examples, this guidance should clarify what MHPAEA requires and provide additional detail about best practices that states can implement as they monitor and enforce federal law. The federal government should provide additional clarity and communication about state regulator roles and responsibilities related to enforcement, including clearer guidance about how corrective action should be taken. This should include:
 - Guidance on the use of Medicaid and private insurance claims data, which is available through State Medicaid offices and, in many states, all payers claim data bases to identify trends that will uncover system-wide violations of the federal parity law. The data would reveal reimbursement patterns from which regulators can readily identify utilization management strategies (notification, authorization, and fail first requirements) that result in disproportionate denials of care for MH/SUD care. The data would also reveal gaps in provider networks by tracking members' disproportionate use of out-of-network services for MH/ SUD services.
 - Specific guidance to state regulators on how to monitor and determine whether network adequacy requirements of the federal MH/SUD parity law

are being met. ASAM appreciates explicit inclusion of MH/SUD service providers in network adequacy requirements for Medicaid and the commercial market and looks forward to continued work by the federal government to ensure these protections are meaningful. The final parity rule identifies standards for provider admission to participate in a network, provider rates, and treatment limitations based on facility type and provider specialty as examples of non-quantitative treatment limitations that must comply with the federal parity law.

- To address the national opioid epidemic and take full advantage of the small number of highly effective, approved medications, we urge the federal regulators to issue clear guidance that:
 - Parity requires coverage of all three medications for opioid dependence, as well as medications for other SUDs; and
 - Use of fail first, prior notification or authorization and other policies that disproportionately restrict access to addiction medications violates parity.
- All enforcement actions and compliance correction plans should be made public on appropriate federal and state websites.
- Denial rates for each benefit classification for MH/SUD and medical/surgical for group health plans should be tracked, collected, and made public on state and federal websites (including the plan's methodology for classifying and tracking such denial rates).
- Health plans should be required to file a compliance plan with federal and state regulators that includes NQTLs used by the plan and information describing how the plan *develops and applies* NQTLs to MH/SUD and medical/surgical disorders covered by the plan. The compliance plan should be made available to consumers and providers upon request. Further, health plans should be required to disclose a comprehensive list of the types of NQTLs that are applied to the MH/SUD benefit in the summary of benefits documents provided to policyholders. Without such a list, MH/SUD consumers have no way to know whether the policy they purchase is accessible and covers essential services for their mental health or addiction disorder.
 - Plans that are not providing this disclosure must be subject to fines.

Task Force Goal 2: Support the development of tools and resources providing a roadmap to parity implementation and enforcement

Enrollees have limited knowledge of their rights and benefits under the parity law. A 2014 [survey](#) by the American Psychological Association found that only 4% of Americans said

they were even aware of MHPAEA. Neither the Administration nor health plans have engaged in any major public awareness campaigns to inform enrollees about the law. The Substance Abuse and Mental Health Services Administration (SAMHSA) has provided information on its website and DOL and Center for Consumer Information and Insurance Oversight (CCIIO) have help lines, but the information provided on the help lines to consumers is too complicated and overly comprehensive for them to understand (e.g., legislative background on HIPAA and MHPAEA). In certain states, state officials have told enrollees that the state is not required to implement or enforce MHPAEA and have outdated information on their website about the law.

Given that the limited enforcement of the law to date has relied on consumer complaints, this lack of public awareness exacerbates the problems with enforcement. As only those who know and understand their rights can complain, complaints are limited and thus enforcement is sparse. Increasing consumer awareness and understanding is another strategy to improve enforcement by driving complaints.

Recommendations:

- A public education campaign on the rights and benefits of the federal parity law should be established, funded, and directed toward consumers and health care providers. This campaign should provide concrete examples of standards that raise “red flags” for potential violations and define a clear path for reporting suspected parity violations.
- A consumer parity portal on relevant state and federal websites should be developed within 6 months to allow consumers to easily access all publicly available parity information and submit complaints to a central online clearinghouse.
- Agencies should clarify how MHPAEA applies across various plan types including appeals, rights, timelines, and agency responsible.
- In conjunction with DOL and HHS, SAMHSA should develop and disseminate materials for providers to help patients and families with appeals. Materials would explain different types of appeals, timelines and how MHPAEA, Employee Retirement Income Security Act (ERISA), and Affordable Care Act (ACA) affect appeals for different plan types as well as to whom consumers should send complaints.

Task Force Goal 3: Develop additional agency guidance as needed to facilitate the implementation of parity

As discussed above, problems with MHPAEA non-compliance, particularly around NQTLs, persist. To ensure compliance with MHPAEA, additional enforceable guidance or

regulations should be released that clarify for plans what practices are and are not parity-compliant and facilitate the implementation of parity.

Recommendations

The Agencies should issue guidance that includes specific examples of methods that group health plans may use for disclosing information in accordance with FAQ #9 including:

- Information regarding the analyses, documentation and testing performed to ensure that each NQTL is comparable and no more stringently applied to the MH/SUD benefit than to the medical/surgical benefit.
- The guidance should include specific examples of NQTL analyses, documentation and testing that are compliant or non-compliant, with respect to NQTLs such as:
 - Medical management standards that limit or exclude benefits based on medical necessity, medical appropriateness or whether the treatment is experimental or investigative
 - Administrative management techniques such as geographic restrictions on locus of treatment not on par with access to other medical facilities
 - Prescription drug formulary
 - Fail first/step therapy or derivatives of such barriers
 - Network admission criteria
 - Provider reimbursement

Conclusion

Thank you again for the opportunity to provide comments. We look forward to working with the Task Force and the Administration in any way we can to ensure MHPAEA's full implementation and enforcement, so that patients can access the addiction treatment services promised under the law. We pledge to do our part in disseminating the final White House Task Force recommendations and forthcoming federal guidance to our members.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Jeffrey Goldsmith MD". The signature is fluid and cursive, with a prominent initial "R" and "J".

R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM
President, American Society of Addiction Medicine

ⁱ The National Center on Addiction and Substance Abuse. (2016). Uncovering Coverage gaps: A Review of Addiction Benefits in ACA Plans. Retrieved from: <http://www.centeronaddiction.org/addiction-research/reports/uncovering-coverage-gaps-review-of-addiction-benefits-in-aca-plans> Accessed August 9, 2016.



**Passport Health Plan Prior Authorization
Buprenorphine-Containing Products**

Note: Form must be completed in full. An incomplete form may be returned.
Information on this form is protected health information and subject to all privacy and security regulations under HIPAA

Patient's Name										Member ID#						
Address										Apt # or Suite #						
City										State		Zip Code				
Phone Number			Weight			Date of Birth (MM/DD/YY)										
- -			lbs			/ /										

Physician's Name										Prescriber's NPI						
Address										Apt # or Suite #						
City										State		Zip Code				
Contact Person																
Contact Person Phone Number					Contact Person Fax Number											
- -					- -											

DRUG REQUESTED (Name):				DOSAGE FORM:		STRENGTH:		QUANTITY PER DAY (SIG):			
DIAGNOSIS:				DIAGNOSIS CODE:			AUTHORIZATION START DATE REQUESTED:				
PLEASE INDICATE WHETHER THIS IS AN INITIAL REQUEST (NEW START), RENEWAL REQUEST, OR A RESTART DUE TO RELAPSE:											

BUPRENORPHINE SINGLE ENTITY PRODUCTS may only be prescribed to members who are pregnant, breastfeeding, have a documented hypersensitivity to naloxone, or the injectable is being administered in a physician's office or healthcare facility. Physicians may not prescribe buprenorphine single entity products because they are less expensive or because that is the only product covered by the patient's insurance.

PLEASE CHECK ONE OF THE FOLLOWING:

- I have billed Passport Health Plan for this member's medication assisted treatment office visit.
- The member paid cash for the medication assisted treatment office visit.

PLEASE CHECK ONE OF THE FOLLOWING IF APPLICABLE & COMPLETE INITIAL OR RENEWAL AS NOTED:

- Member is new to therapy. **INITIAL REQUEST**
- Member is new to Passport: Continuity of Care protocol may apply. MRx will verify eligibility. **INITIAL REQUEST**
- Member is new to this prescriber; previous therapy was authorized under Passport; prescriber does NOT have access to previous medical records. **INITIAL REQUEST**
- Member is new to this prescriber; previous therapy was authorized under Passport; prescriber DOES have access to previous medical records. **RENEWAL REQUEST**

TREATMENT PLAN: _____

ANTICIPATED LENGTH OF THERAPY: _____



Note: Form must be completed in full. An incomplete form may be returned.
Information on this form is protected health information and subject to all privacy and security regulations under HIPAA

DOSE LIMITATIONS: Buprenorphine/Naloxone (Suboxone®) therapy is limited to 16mg/day (or equivalent for other buprenorphine-containing products). Requests for doses greater than 16mg/day (or equivalent) will only be authorized for **FOUR WEEKS** at a time and will require explanation to support dose and must include a plan for dose tapering. This must be completed for every reauthorization for doses greater than 16mg/day. See #9 under **RENEWAL REQUEST**.

INITIAL REQUEST (PLEASE COMPLETE SECTION BELOW AND CHECK ALL APPLICABLE BOXES. FOR REAUTHORIZATIONS PLEASE SKIP TO RENEWAL SECTION): If the criteria below are met, an initial **MAXIMUM OF THREE MONTHS** of a buprenorphine-containing product will be authorized. If the criteria are not met, physician review will be necessary to determine whether other factors (e.g. age, co-morbidities, social situation, prior treatment, etc) would support medical necessity for the initiation or re-initiation of a buprenorphine agent. **Additional information section is provided for necessary explanations.**

1	<input type="checkbox"/>	<input type="checkbox"/>	Prescriber has been issued an "X" DEA license number to prescribe buprenorphine-containing products for the treatment of opioid dependence. "X" DEA license number: _____
	YES	NO	
2	<input type="checkbox"/>	<input type="checkbox"/>	Prescriber utilized a diagnostic and/or screening tool (e.g. Diagnostic and Statistical Manual of Mental Disorders, DAST and/or COWS Assessment for diagnosis of opioid dependence and/or withdrawal. Specific tool used: _____
	YES	NO	
3	<input type="checkbox"/>	<input type="checkbox"/>	Prescriber has obtained and reviewed a KASPER report for the patient for the twelve (12) month period immediately preceding the initial patient encounter. PRESCRIBER MUST DOCUMENT DATE AND REQUEST NUMBER. Date: ____/____/____ Request number: _____
	YES	NO	
4	<input type="checkbox"/>	<input type="checkbox"/>	Prescriber has performed and documented a drug screen. PRESCRIBER MUST DOCUMENT DATE OF DRUG SCREEN AND RESULTS. Date: ____/____/____ Results: _____
	YES	NO	
5	<input type="checkbox"/>	<input type="checkbox"/>	Member has co-occurring psychiatric condition(s), which could interfere with compliance to therapy. If YES, is psychiatric condition stabilized and/or treated? <input type="checkbox"/> Yes <input type="checkbox"/> No
	YES	NO	
6	<input type="checkbox"/>	<input type="checkbox"/>	THIS IS AN INFORMATIONAL REQUEST AND DOES NOT FACTOR INTO PA APPROVAL OR DENIAL: Member has had an emergency department visit or inpatient hospitalization due to medical/psychiatric complications of opioid use (e.g. infection, acute suicidal ideation, etc.). PRESCRIBER MUST DOCUMENT DATE(S) AND MEDICAL/PSYCHIATRIC COMPLICATION(S) ADDRESSED. Depending on the frequency and severity of acute visits, the member may be referred to case management for additional support.
	YES	NO	
7	<input type="checkbox"/>	<input type="checkbox"/>	Prescriber or other professional is rendering substance use disorder counseling for the member. NOTE: A 12-step program ALONE is considered social support and not professional counseling. PRESCRIBER MUST DOCUMENT THE NAME OF THE LICENSED PROFESSIONAL OR ORGANIZATION. Name: _____
	YES	NO	
8	<input type="checkbox"/>	<input type="checkbox"/>	Risks/benefits of using buprenorphine-containing products have been explained to the member, including the risks of using them with alcohol or benzodiazepines.
	YES	NO	
9	<input type="checkbox"/>	<input type="checkbox"/>	<i>Statement of Understanding Form</i> (member consent form) has been reviewed and signed by both the member AND prescriber. ATTACH SIGNED COPY OF CONSENT FORM. NOTE: If the prescriber has an existing treatment agreement form, this may be submitted instead (must be signed by both the member AND prescriber).
	YES	NO	
10	<input type="checkbox"/>	<input type="checkbox"/>	FEMALE MEMBERS ONLY: Member has been given a pregnancy test and advised of the risk of neonatal abstinence syndrome. For female patients who are not of reproductive potential, please document the reason (e.g. post menopause, post hysterectomy, etc.).
	YES	NO	
11	<input type="checkbox"/>	<input type="checkbox"/>	FEMALE MEMBERS ONLY: Member is pregnant or breastfeeding. Prescriber has consulted with another physician (who is certified by the American Board of Addiction Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry or from an obstetrician or maternal-fetal medicine specialist who is also qualified to prescribe buprenorphine) prior to prescribing a buprenorphine agent. <input type="checkbox"/> Yes <input type="checkbox"/> No.
	YES	NO	
			Certification or specialty of consulted prescriber: _____

Please see the next page for RENEWAL REQUEST questions.

Note: Form must be completed in full. An incomplete form may be returned.
 Information on this form is protected health information and subject to all privacy and security regulations under HIPAA

RENEWAL REQUEST (PLEASE COMPLETE SECTION BELOW AND CHECK ALL APPLICABLE BOXES): If the criteria below are met, a **MAXIMUM OF SIX MONTHS** of a buprenorphine-containing product will be authorized. If the criteria are not met, physician review will be necessary to determine whether other factors (e.g. age, co-morbidities, social situation, prior treatment, etc.) would support medical necessity for the initiation or re-initiation of a buprenorphine agent. **Additional information section is provided for necessary explanations.**

FOR FEMALE MEMBERS ONLY: Please continue to monitor pregnancy status and provide education on the risk of neonatal abstinence syndrome, throughout the duration of treatment. If member is pregnant or breastfeeding, please consult with another physician (who is certified by the American Board of Addiction Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry or from an obstetrician or maternal-fetal medicine specialist who is also qualified to prescribe buprenorphine) for an opinion as to whether the potential benefit of buprenorphine-mono-product or buprenorphine-combined-with-naloxone use outweighs the potential risk of use.

1	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Prescriber attests that member has demonstrated consistent use of the requested medication. If inconsistent use is noted, then a written explanation as to why a buprenorphine agent should be continued despite non-compliance would be needed.
2	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Prescriber attests that at least eight (8) drug screens will/have been performed within each twelve (12) month treatment period. PRESCRIBER MUST DOCUMENT DATES AND ATTACH RESULTS FROM LAST TWELVE (12) MONTHS. Dates: _____
3	<input type="checkbox"/> YES	<input type="checkbox"/> NO	All drug screens have been positive for buprenorphine and/or buprenorphine metabolite (i.e. norbuprenorphine); if any drug screens were negative for buprenorphine and/or norbuprenorphine, the prescriber must attach an explanation of results.
4	<input type="checkbox"/> YES	<input type="checkbox"/> NO	All drug screens have been negative for <i>unauthorized</i> opiates; if any drug screens were positive for <i>unauthorized</i> opiates, the prescriber must attach an explanation of results.
5	<input type="checkbox"/> YES	<input type="checkbox"/> NO	At least two (2) drug screens within each twelve (12) month treatment period were random and coupled with a pill count. PRESCRIBER MUST DOCUMENT DATES AND ATTACH RESULTS FROM LAST TWELVE (12) MONTHS. Dates: _____
6	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Prescriber has obtained and reviewed monthly KASPER reports and certifies reports showed no unauthorized concurrent opioid fill(s). DOCUMENT DATES & REQUEST NUMBERS FOR ALL KASPER REPORTS SINCE THE LAST AUTH. Date: ___/___/___ Request #: _____ Date: ___/___/___ Request #: _____ Date: ___/___/___ Request #: _____ Date: ___/___/___ Request #: _____ Date: ___/___/___ Request #: _____ Date: ___/___/___ Request #: _____
7	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Member has had an opioid relapse with <i>unauthorized</i> opioids. PRESCRIBER MUST DOCUMENT THE APPROXIMATE DATE AND HOW THE RELAPSE WAS MANAGED. _____ _____
8	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Prescriber or other professional is rendering substance use disorder counseling for the member. NOTE: A 12-step program ALONE is considered social support and not professional counseling. PRESCRIBER MUST DOCUMENT THE NAME OF THE LICENSED PROFESSIONAL OR ORGANIZATION AND DATES OF ALL COUNSELING SESSIONS SINCE LAST AUTHORIZATION. Name and Dates: _____
9	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Member has co-occurring psychiatric condition(s) which could interfere with compliance to therapy. Is psychiatric condition stabilized and/or treated? <input type="checkbox"/> Yes <input type="checkbox"/> No
10	<input type="checkbox"/> YES	<input type="checkbox"/> NO	The requested dose is > 16mg/day of Suboxone® (or equivalent for other buprenorphine-containing products). PRESCRIBER MUST PROVIDE AN EXPLANATION TO SUPPORT THE DOSE AND MUST DOCUMENT A PLAN FOR DOSE TAPERING.

RENEWAL ITEM REF #	RATIONALE AND/OR ADDITIONAL INFORMATION, WHICH MAY BE RELEVANT TO THE REVIEW OF THIS PRIOR AUTHORIZATION REQUEST (IF CRITERIA LISTED ABOVE ARE NOT MET, ADDRESS THOSE ISSUES AND EXPLAIN WHY A BUPRENORPHINE-AGENT IS MEDICALLY NECESSARY):

PRESCRIBER'S SIGNATURE: _____ **DATE:** _____

Statement of Understanding Form – Taking Buprenorphine-Containing Products

I, [insert name] _____, have talked to my provider about taking buprenorphine-containing medicines. I understand and agree to the following:

- I have decided to take this medicine to help treat my addiction to narcotic drugs.
- I know from talking to my provider that there are risks and possible side effects linked to taking this medicine.
- I agree to follow the therapy as ordered by my provider.
- I have had the chance to ask questions about this product, other treatment options, and the risks of treatment. I have enough information to understand my treatment.
- I will tell my provider who is prescribing this medicine about any other provider or dentist appointments. I will tell my provider about any prescription and non-prescription medicines I am taking.
- I have been given a copy of this Statement of Understanding Form.

To help make my treatment a success, I agree to:

- Go to all of my follow-up visits.
- Take any alcohol or drug tests my provider orders. I know from talking with my provider that it is unsafe to mix this medicine with alcohol and other drugs.
- Store my medicine in a safe place. I will not share my medicine with anyone. I know it can be unsafe for others.
- Take this medicine as ordered by my provider. To get the most benefit from the medicine, I will not skip any doses. I have been told how to take this medicine. I will place it under my tongue to dissolve (melt) and be absorbed.
- Get my prescriptions for this medicine only from the provider/provider group listed on this agreement.
- Go to counseling as part of treating my addiction.

By signing here, I agree to ALL of the bullet points on this form.

Signature: _____ Date: _____

Prescriber's Signature: _____ Date: _____

PROV40935 APP_2/12/2015



Medication-assisted Treatment Prior Authorization Form

This form is required for prior authorization requests for buprenorphine and buprenorphine-containing medications. Please fax the completed form to 1-866-930-0019. Prior authorization requests for medication-assisted treatment are not accepted over the phone.

Member information	Name:	Date of birth:
	Plan: Medicaid	
	Member ID:	Sex: <input type="checkbox"/> M <input type="checkbox"/> F
	Address:	Phone:
	City, state, ZIP:	
Prescriber information	Name:	
	Office contact:	DEA:
	Office address:	XDEA:
	City, state, ZIP:	NPI:
	Phone:	Fax:
	Prescriber certification: <input type="checkbox"/> Substance Abuse and Mental Health Services Administration (SAMHSA) waiver <input type="checkbox"/> American Society of Addiction Medicine (ASAM)	
	1. Prescriber is enrolled as a valid CareSource prescriber. <input type="checkbox"/> Yes <input type="checkbox"/> No 2. Prescriber certifies he/she is treating the patient for a substance-use disorder and billing for such service(s) through the member's benefit and health plan. <input type="checkbox"/> Yes <input type="checkbox"/> No 3. Prescriber is compliant with all stipulations in the practice act regulations when dispensing MAT. <input type="checkbox"/> Yes <input type="checkbox"/> No	
Diagnosis criteria	Diagnosis:	ICD-10:
	1. Patient has signed an informed consent or treatment contract. <input type="checkbox"/> Yes <input type="checkbox"/> No 2. Patient's treatment plan includes at least one monthly visit with the treating physician or his/her qualified agent. <input type="checkbox"/> Yes <input type="checkbox"/> No	

3. Prescriber has explained the risks and benefits of using MAT to the patient and warned the patient to avoid concomitant use with alcohol, stimulants, opioids or benzodiazepines. Yes No

Please indicate whether this is: an initial request a continuation request

Requested MAT

- | | |
|--|---|
| <input type="checkbox"/> Buprenorphine 2 mg tablet | <input type="checkbox"/> Suboxone 4/1 mg film |
| <input type="checkbox"/> Buprenorphine 8 mg tablet | <input type="checkbox"/> Suboxone 8/2 mg film |
| <input type="checkbox"/> Bunavail 2.1/0.3 mg buccal film | <input type="checkbox"/> Suboxone 12/3 mg film |
| <input type="checkbox"/> Bunavail 4.2/0.7 mg buccal film | <input type="checkbox"/> Zubsolv 1.4/0.36 mg tablet |
| <input type="checkbox"/> Bunavail 6.3/1 mg buccal film | <input type="checkbox"/> Zubsolv 2.9/0.71 mg tablet |
| <input type="checkbox"/> Buprenorphine/naloxone (Suboxone) 2/0.5 mg tablet | <input type="checkbox"/> Zubsolv 5.7/1.4 mg tablet |
| <input type="checkbox"/> Buprenorphine/naloxone (Suboxone) 8/2 mg tablet | <input type="checkbox"/> Zubsolv 8.6/2.1 mg tablet |
| <input type="checkbox"/> Suboxone 2/0.5 mg film | <input type="checkbox"/> Zubsolv 11.4/2.9 mg tablet |

* Requests made for a dose greater than 16 mg daily **must** be prescribed by, or in consultation with, a certified addiction specialist or psychiatrist.

Check one: Induction Stabilization Maintenance

Induction date (required):

Dose and frequency:

Quantity:

Daily dose:

Expected length of therapy:

Buprenorphine (without naloxone) tablet requests only (Clinical criteria must meet all initial criteria AND one of the following):

Check one: Member is pregnant Two-day induction to Suboxone therapy Hypersensitivity to naloxone

For female patients

1. Is the patient pregnant or nursing? Yes No

If yes, prescriber must be certified in addiction medicine, psychiatry, obstetrics or maternal-fetal medicine by the American Board of Addiction Medicine, the American Board of Medical Specialties (ABMS) or an American Osteopathic Association (AOA)-certifying board, or documentation must be submitted that the prescriber consulted with a provider with the previously mentioned credentials.

2. Has the patient been counseled on the risks of neonatal abstinence syndrome? Yes No

Required for review: Documentation of recent pregnancy test, documentation of inability to conceive, documentation of counseling as to the risk of neonatal abstinence syndrome and certified prescriber.

Required state-controlled substance-reporting service (OARRS, KASPER, etc.) request number:

Date last queried: Number of current narcotic prescriptions:

Date of last controlled substance filled:

Initial treatment requests only

1. Has the patient failed a prior attempt with an opiate agonist treatment in the past 12 months?
 Yes No

2. Has the prescriber identified any opioid, benzodiazepine, sedative or stimulant medications prescribed 14 days prior to requested initiation of MAT?
 Yes No

2a. If yes, have they been discontinued?
 Yes No

3. If no to 2a, please refer to criteria for documentation that must be submitted for approval. For concomitant use, the prescriber must be certified through the American Board of Addiction Medicine or the American Board of Medical Specialties (ABMS) in psychiatry, or have consulted with such a certified practitioner. Please document specialty or name and specialty of consulted prescriber.

4. Prescriber has included documentation demonstrating the patient was referred or has already started behavioral and psychosocial therapy services.
 Yes No

5. Prescriber obtained a required state-controlled substance report (OARRS, KASPER, etc.) no earlier than two days prior to the date of this request.
 Yes No

Continuation requests only

1. The prescriber previously submitted all required initial treatment documentation.
 Yes No

2. The prescriber included documentation of monthly negative opiate urine tests since last authorization. (All monthly urine screenings must be included for request to be considered.)
 Yes No

3. Patient is compliant with **no gaps** in therapy since initial authorization. (If not, please attach explanation.)
 Yes No

4. The prescriber included documentation that demonstrates evaluation and clinical reasoning for continuation of MAT.
 Yes No

5. The patient continues active participation in evidence-based drug abuse counseling methods. (Please attach documentation.)
 Yes No

Required for review: Documentation of all monitoring tools (e.g., urine analysis, drug screen), including medication compliance checks that occurred prior to or in between requests. Abnormal findings must be explained.

Complete the following information regarding required state-controlled substance reports (OARRS, KASPER, etc.):

Report	Query date	Report request number	Report	Query date	Report request number
1			4		
2			5		

3

6

Tapering therapy (Must be attempted after every six-month interval of treatment. Complete only if applicable.)

Has the patient attempted a two-week trial of a lower buprenorphine dose?

Yes

No

Include dose level attempted, date and length of trial: (Please include documentation if attempt failed.) _____

Counseling documentation (the following must be submitted with each PA request):

Required for review: Documentation of the physician rendering counsel must be submitted with each request if the prescribing physician is not a psychiatrist or certified addiction specialist. If another physician is providing counseling, documentation on that provider's letterhead must be submitted, confirming the patient is undergoing active counseling (including objective psychosocial and behavioral modification).

Other pertinent information (attach other pages if needed):

I attest, by my signature, that the information above is true and accurate to the best of my knowledge and has been documented appropriately in the patient's medical records.

Prescriber signature

Date

UTAH DEPARTMENT OF HEALTH, PRIOR AUTHORIZATION REQUEST FORM

SUBOXONE, ZUBSOLV, BUNAVAIL (buprenorphine/naloxone)

Please see separate criteria for buprenorphine single-agent oral products

Patient name: _____ Medicaid ID #: _____

Prescriber Name: _____ Prescriber NPI#: _____ Contact person: _____

Prescriber Phone#: _____ Extension/Option: _____ Fax#: _____

Pharmacy: _____ Pharmacy Phone#: _____ Fax #: _____

Pharmacy NPI: _____ Strength: _____ Frequency/Day: _____

All information to be legible, complete and correct or form will be returned

FAX DOCUMENTATION FROM PROGRESS NOTES

AND THIS COMPLETED FORM TO 855-828-4992

If the prescriber desires to provide additional information or detail, a letter of medical necessity will be accepted as a supplement to, but not a replacement for, progress notes.

INITIAL CRITERIA:

- Minimum age requirement: 16 years old
- Documented diagnosis of opioid dependence
- Prescribing physician must provide their X-DEA number: _____
- Evidence supplied of plans for on-going treatment monitoring that includes drug urine screening, or DOPL reports, or random pill counts
- Description of the psychosocial support to be received by patient, as indicated by chart notes or a brief letter of medical necessity
- A treatment plan that includes a tapering plan and discontinuation of pharmacotherapy
- No concomitant therapy with Vivitrol (naltrexone)
- No concomitant therapy with opiate analgesics

AUTHORIZATION:

Initial 18-month authorization at a maximum of 24mg-6mg/day (Suboxone), 17.1mg-4.2mg/day (Zubsolv) or 12.6mg-2.1mg/day (Bunavail).

RE-AUTHORIZATION:

Re-authorization period is 18-months at a maximum dose of 24mg-6mg/day (Suboxone), 17.1mg-4.2mg/day (Zubsolv) or 12.6mg-2.1mg/day (Bunavail) if the following criteria are met:

- Letter of explanation detailing why an additional approval is needed
- Evidence of psychosocial support received by patient
- Evidence that a taper plan has been attempted, and if failed, why
- Detailed plans for immediate taper if initial taper failed
- A negative urine screen completed within 14 days of reauthorization start date
- No concomitant therapy with Vivitrol (naltrexone)
- No concomitant therapy with opiate analgesics

NOTE: Treatment will only be covered up to 36 months (18 month initial authorization and 18 month re-authorization).

NDC CHANGES: NDC changes for dosage tapering must be submitted in an updated letter of medical necessity, faxed to 855-828-4992

04/10/2015

<http://health.utah.gov/medicaid/pharmacy>



Buprenorphine Prior Authorization Form

CONTACT INFORMATION

Patient Name: _____ Patient ID: _____ Patient DOB: ____/____/____
Patient Address: _____ Patient Phone: (____) _____
City: _____ State: _____ Zip Code: _____
Prescribing Physician: _____ NPI: _____ X#: _____
Physician Address: _____
City: _____ State: _____ Zip Code: _____
State License: _____
Office Contact: _____ Office Phone: (____) _____ Office Fax: (____) _____

PROFESSIONAL INFORMATION

Medication Requested: _____
Dosage Strength Requested: _____ Quantity per month: _____ Directions for Use: _____
Patient Diagnosis: _____ Other relevant Diagnoses: _____
Induction Phase: _____ Maintenance Phase: _____ Psychosocial Treatment (for maintenance treatment): Yes No
Dates and results of Toxicology Testing: _____

ADDITIONAL QUESTIONS

Has the patient been advised of the risk of concomitant use of alcohol, benzodiazepines and other sedatives? Yes No
Will the patient be monitored during therapy for signs and symptoms of abuse/misuse as well as compliance and the potential diversion to others? Yes No
Will there be ongoing assessment as to the continued need for Buprenorphine therapy and consideration of taper and discontinuation if clinically appropriate? Yes No
For women of child bearing age, appropriate assessment of possibility of pregnancy? Yes No
In States with Prescription Monitoring Programs, has it been reviewed? Yes No
For patients with co-occurring behavioral health disorders, referral to mental health assessment and/or treatment as indicated? Yes No
For dosing higher than 24mg/day (Suboxone/Subutex), 17.1mg/day (Zubsolv) or 12.6mg/day (Bunavail), documentation as to rationale: _____

Is the prescriber treating more than 100 patients?: Yes No
Will the patient be using any short or long acting opiates concurrently with the Buprenorphine?: Yes No
Other/Supporting information for this request: _____

Physician Signature: _____ Date and Time: _____