

30 de mayo de 2019

**A TODOS LOS PROVEEDORES MÉDICOS, HOSPITALARIOS Y DE SERVICIOS ANCILARES
ESTRATEGIAS DE MANEJO DE OPIOIDES PARA EL PLAN DE SALUD DEL GOBIERNO DE
PUERTO RICO, VITAL**

Estimado(a) proveedor(a):

En el Plan de Salud Menonita – Vital, nuestro compromiso es trabajar con usted de manera integrada y coordinada para un mejor manejo de los pacientes que atendemos en conjunto. Como ente facilitador, es nuestra responsabilidad proveerle toda la información necesaria y relevante para sus futuras intervenciones con los pacientes al momento en que llegan a su oficina para recibir su evaluación de salud.

En esta ocasión, le notificamos sobre las estrategias que ASES, AMSSCA, CDC y CMS están utilizando para el manejo de la sobre utilización de opioides. Se incluyen diferentes materiales informativos de las agencias previamente mencionadas. El material informativo será dividido en tres envíos, que recibirá semanalmente.

A modo de recordatorio incluimos la Carta Normativa de ASES 18-09-18 del 18 de septiembre de 2018. También encontrará el anejo a esta carta circular la cual recomienda a los proveedores registrarse en el Programa de Seguimiento de Medicamentos Recetados, PDMP por sus siglas en inglés. Les exhortamos a que se registren en el PMP Aware (<https://puertorico.pmpaware.net/login>). En los materiales compartidos encontrará un folleto que lo ayudará en el proceso. Confiamos que estos materiales sean de utilidad para su práctica diaria. Como siempre, contamos con su colaboración. Nos mantenemos a su orden para cualquier duda o pregunta.

Centro de Servicio al Proveedor
1-855-297-0140 (libre de cargos)
lunes a viernes de 7:00 a.m. a 7:00 p.m.
<http://psmconnet.psmpr.com>

Cordialmente,



Glorymar Santiago Alicea, PharmD
Directora del Departamento de Farmacia



Gregorio A. Cortés Soto, MD
Principal Oficial Médico



GOBIERNO DE PUERTO RICO
Administración de Seguros de Salud

Hon. Ricardo A. Rosselló Nevares
Gobernador

Sra. Angela M. Avila Marrero
Directora Ejecutiva

Carta Normativa 18-09-18

18 de septiembre de 2018

A: Grupos Médicos Primarios y Proveedores Participantes del Plan de Salud del Gobierno

Asunto: Estrategias para el manejo de la sobreutilización de Opioides en el Plan de Salud del Gobierno

Efectivo el 16 de octubre de 2018, el Plan de Salud de Gobierno estará adoptando medidas para prevenir y combatir la crisis relacionada a la mal utilización de los opioides. En la *"Política para Combatir el Mal Uso de Opioides en MI Salud"* se resumieron las guías del Centro para el Control y la Prevención de Enfermedades (CDC por sus siglas en inglés) para el uso de opioides. El propósito de esta Carta Normativa es detallar las estrategias específicas, basadas en las guías del CDC, a ser implementadas para contribuir a la contención de esta epidemia.

1. Nuevos límites de prescripción para los pacientes "Naïve" o considerados nuevos en opioides de corta duración:

- a. Se implementará un edicto de seguridad para limitar la prescripción inicial de opioides para el tratamiento del dolor agudo a no más de **7 días** de suministro.
- b. Las recetas que sean para pacientes "Naïve" y contengan más de **7 días** de suministro rechazarán en el punto de venta (la farmacia).
- c. Los edictos no serán aplicados a los pacientes que se identifican con diagnóstico de cáncer.
- d. Paciente "Naïve" a opioides se define como, paciente que no tiene uso de opioides en los pasados 60 días.
- e. Paciente "Naïve" no podrá comenzar su tratamiento con opiodes de larga duración, solo podrán utilizar opiodes de corta duración.
- f. A estos pacientes identificados como "Naïve" en opiodes se le aplicarán un máximo de tabletas diarias y el suministro deberá ser de 3 a 7 días (dependiendo del formulario) dentro de un período de 30 días para el tratamiento del dolor agudo, **como explicaremos más adelante en la tabla.**
- g. La farmacia evaluará tanto la cantidad de días, como la cantidad de tabletas diarias y deberá ajustar la cantidad al límite permitido, de acuerdo con el mensaje de alerta que reciba.
- h. Los beneficiarios tendrán el derecho a solicitar una determinación de cubierta, ya sea para tratamiento por más de 7 días o mayor cantidad de tabletas diarias solo en aquellos casos que el médico que prescribe justifique la necesidad de llevar una cantidad mayor a la establecida.
- i. Los formularios de Dental, Sub Físico y Formulario de Emergencia Integrado (FEI, por sus siglas en español) mantendrán las reglas de días de suplido actuales.
- j. Los límites de días de suplido por formulario se detallan a continuación:



Formularios	Días de suplido	Aplicará un máximo de unidades diarias
Dental	Una receta de 3 días de suplido en 30 días	X
Sub Físico, FEI	Una receta de 5 días de suplido en 30 días	X
Salud Física, Ob-Gyn	Una receta de 7 días de suplido en 30 días	X
Oncología	No cambios	

- k. Los nuevos límites de cantidad que permitirán despachar un máximo de unidades diarias para los pacientes nuevos se implementarán como se describe a continuación:

Nombre del Opioide de Corta Duración en FMC*	Nombre de Referencia	Formularios	Cantidad Máxima por Día para pacientes Naïve (Nuevos en Opioides de Corta Duración)
Hydromorphone HCl Tab 2 MG	Dilaudid	Salud Física	6 tabletas diarias/ 7 días de suplido dentro de un periodo de 30 días
Hydromorphone HCl Tab 4 MG	Dilaudid	Salud Física	3 tabletas diarias/ 7 días de suplido dentro de un periodo de 30 días
Hydromorphone HCl Tab 8 MG	Dilaudid	Salud Física	1 tableta diaria/ 7 días de suplido dentro de un periodo de 30 días
Morphine Sulfate Tab 15 MG	Morphine Sulfate 15	Salud Física	3 tabletas diarias/ 7 días de suplido dentro de un periodo de 30 días
Morphine Sulfate Tab 30 MG	Morphine Sulfate	Salud Física	1 tableta diaria/ 7 días de suplido dentro de un periodo de 30 días
Morphine Sulfate Oral Soln 10 MG/5ML	Morphine Sulfate liq	Salud Física	20 ml diarios/ 7 días de suplido dentro de un periodo de 30 días
Tramadol HCl Tab 50 MG	Ultram	Salud Física	3 tabletas diarias/7 días de suplido dentro de un periodo de 30 días
		Sub-Física, FEI	3 tabletas diarias/5 días de suplido dentro de un periodo de 30 días
Oxycodone w/ Acetaminophen Tab 5-325 MG	Percocet	Salud Física, Ob-Gyn	6 tabletas diarias/7 días de suplido dentro de un periodo de 30 días
Acetaminophen w/ Codeine Tab 300-30 MG	Tylenol with Codeine #3	Salud Física	6 tabletas diarias/ 7 días de suplido dentro de un periodo de 30 días
		Dental	6 tabletas diarias/3 días de suplido dentro de un periodo de 30 días
		Sub-Física, FEI	6 tabletas diarias/5 días de suplido dentro de un periodo de 30 días

Nombre del Opiode de Corta Duración en FMC*	Nombre de Referencia	Formularios	Cantidad Máxima por Día para pacientes Naïve (Nuevos en Opioides de Corta Duración)
Hydrocodone-Acetaminophen Tab 5-325 MG	Norco, Lortab, Lorcet	Salud Física	6 tabletas diarias/7 días de suplido dentro de un periodo de 30 días
		Dental	6 tabletas diarias/3 días de suplido dentro de un periodo de 30 días

*Estos opioides se encuentran también en el formulario de Oncología y los nuevos límites de prescripción no le serán aplicados, se cubrirán todos en suplidos que no excedan 30 días.

2. Nuevo edito para los pacientes con utilización crónica de opioides de corta y larga duración:

- a. Se implementará un edito de seguridad para pacientes con utilización crónica utilizando la validación en el sistema de adjudicación del cálculo de Miligramos Equivalentes de Morfina (MME) acumulados por día.
- b. Sistema primero verifica si el paciente tiene historial de uso previo en los pasados sesenta (60) días, de NO tener uso previo, se considera "Naive" y le aplican los límites de prescripción explicados en la sección #1.
- c. Los editos no serán aplicados a los pacientes que se identifican con diagnóstico de cáncer.
- d. De haber uso previo durante este término, el sistema de adjudicación calculará la dosis acumulativa de morfina (MME) por día.
 - i. Si la dosis acumulativa, $MME/día \leq 89$ la reclamación será aprobada.
 - ii. Si la dosis acumulativa, $MME/día \geq 90$ hasta 199, sistema detendrá la reclamación y emitirá un mensaje de alerta al farmacéutico de que la reclamación sobrepasa el límite diario de MME permitido para ese opioide.
 - iii. El farmacéutico deberá documentar al dorso de la receta la consulta realizada al médico.
- e. Si la dosis acumulativa, $MME/día \geq 200$, el sistema detendrá la reclamación y solo será aprobada luego de una determinación de cubierta. El farmacéutico deberá comunicarse con la aseguradora correspondiente para evaluar el caso.

3. Editos de seguridad adicionales

- a. **Edito de seguridad para la combinación de potenciadores y opioides.** Los potenciadores son medicamentos que se utilizan para intensificar los efectos del opioide. ASES recomienda precaución en el uso concomitante de opioides y sus potenciadores. Se estará emitiendo un mensaje de alerta en el punto de servicio para que el farmacéutico realice una intervención y evite posibles riesgos a todos los pacientes relacionados a esta combinación de medicamentos.
- b. Los editos de seguridad se aplicarán a los siguientes grupos de potenciadores como se describen a continuación:

Edito de DUR	Clase Terapéutica	Tipo de edito
Terapia Duplicada	Opioides indicados para el dolor (que no sean buprenorphine ni buprenorphine/naloxone indicados para tratamiento de dependencia a opioides)	Sistema rechazará reclamaciones con esta duplicidad

Terapia Duplicada	Benzodiazepinas	“Hard Reject” – no permite códigos de “override”
Interacción de Drogas	Opioide + benzodiazepinas	Sistema emitirá mensaje de alerta al farmacéutico para intervención
Interacción de Drogas	Opioide + Sedativos Hipnóticos	Sistema emitirá mensaje de alerta al farmacéutico para intervención
Interacción de Drogas	Opioide + barbiturates	Sistema emitirá mensaje de alerta al farmacéutico para intervención
Interacción de Drogas	Opioid + buprenorphine, Opioid + buprenorphine/naloxone indicados para tratamiento de dependencia a opioides.	El sistema de adjudicación no permitirá el despacho de opioides a pacientes en buprenorfina.

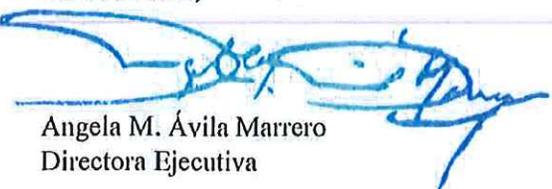
4. Otros cambios, se describen a continuación y aplicarán únicamente a los formularios mencionados:

Nombre del medicamento genérico	Nombre de Referencia	Formulario	Cambio
Butalbital-acetaminofen- cafeina 50-325-40 mg tabs	Fioricet	Salud Física	Nuevo límite de prescripción de 28 tabletas para 7 días de suplido
		Sub Físico, FEI	Nuevo límite de prescripción de 28 tabletas para 5 días de suplido
Meperidine HCl Inj 50 MG/ML	Demerol	Salud Física	Se cubrirá un (1) vial para 30 días de suplido
Meperidine HCl Inj 100 MG/ML	Demerol	Salud Física	Se cubrirá un (1) vial para 30 días de suplido
Morphine Sulfate Oral Soln 100 MG/5ML (20 MG/ML)	Morphine Sulfate (Concentrate)	Salud Física	Se remueve de formulario efectivo inmediatamente.

Exhortamos a los médicos que compartan esta carta con todo el personal que trabaje en su oficina y puedan explicarles los detalles e implicaciones que conlleva. Para información adicional relacionada a este comunicado puede comunicarse con Triple S- Salud al Libre de Costo 1-800-981-1352 o / Área metro 787-775-1352, TTY/TDD 1-855-295-4040 todos los días de la semana las 24 horas.

Estas medidas adaptadas de las guías del CDC y de CMS serán implementadas para la seguridad de nuestros pacientes. ASES continuará implementando iniciativas como esta que ayuden a combatir la epidemia de opioides y colaborará con las demás agencias locales en esta importante labor. Agradecemos la cooperación que siempre brindan a la ASES.

Cordialmente,



Angela M. Ávila Marrero
Directora Ejecutiva



Puerto Rico Health Insurance Administration Policy to Combat Opioid Misuse in MI Salud beneficiaries

I. PURPOSE:

To define the Puerto Rico Health Insurance Administration (ASES, for its acronym in Spanish) policy to combat and prevent misuse of prescription opioid drugs under MI Salud, also known as the Government Health Insurance Plan (GHIP). The goal of this policy is to ensure safe, appropriate utilization and control of short acting opioids, prevent overutilization and reduce risk of long term use and diversion.

II. POLICY:

Beginning October 16, 2018, as part of the standard formulary update process, members utilizing short acting opioid medications will be subject to limit changes. Changes follows Centers for Medicare & Medicaid Services (CMS) recommendations in 2019 Call Letter which are aligned with Centers for Disease Control (CDC) guidelines updated in 2016 and clinically-based prescribing habits on the number of Morphine Milligram Equivalents (MME) a member can receive at any given time. There will be separate limits for members who are new to therapy and members who are existing users of opioids, as outlined below.

Prior Authorization (PA) may be pursued if clinically necessary, the Managed Care Organizations (MCOs) will maintain a standardized procedure for making timely and appropriate coverage determination decisions in accordance with the established criteria as approved by ASES' Pharmacy and Therapeutics (P&T) Committee.

III. SCOPE

This policy applies to ASES' contracted pharmacy benefit management (PBM) organization, MCOs and their MI Salud providers including, but not limited to, physicians, hospitals, behavioral facilities, ambulatory facilities, and pharmacies prescribing and/or dispensing outpatient drugs.

IV. BACKGROUND

According to the CDC, the lowest effective dose of short-acting opioids should be prescribed for no more than three (3) days; more than 7 days should rarely be needed (<https://www.cdc.gov/drugoverdose/prescribing/guideline.html>). Short-acting opioids (i.e. immediate- or regular-release oral morphine, hydromorphone, oxycodone, and codeine) are indicated for short-term relief of moderate to severe pain on an "as needed" basis. These medications are often used in conjunction with a long acting opioid to help relieve breakthrough pain in patients with cancer.

The CDC also recommends use non-opioid treatments first. There is insufficient evidence to support efficacy of long term opioids and opioids are not first line or routine therapy for chronic pain outside of cancer treatment, palliative care, and end of life care. These substances carry with them the potential for harm from adverse drug events and/or overdose. Opioid drugs also have substantial misuse liability and are often implicated among persons who have developed a substance misuse disorder. Concomitant use of benzodiazepines significantly increases the risk of harm from opioids.

Clinicians must use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day. Higher dosages

of opioids are associated with higher risk of overdose and death; evidence shows that limiting or reducing MME per day helps avoid harmful effects of opioids and promotes patient safety. Opioid daily doses above 50 MME/day increase the risk of overdose by at least double.

V. POLICY DESCRIPTION

While most beneficiaries utilize and clinicians prescribe opioids in ways that are medically appropriate, opioid overutilization is nonetheless a significant concern for the MI Salud program, and ASES is helping MCOs and all providers identify individuals potentially at risk for opioid abuse through programs like this to **Combat Opioid Misuse in MI Salud Beneficiaries**.

A. P&T Opioid Formulary Design Approach

1. Opioids are selected for formulary inclusion based on the recommendations of robust, reliable clinical guidelines, such as:
 - i. Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain
 - ii. The American Society of Interventional Pain Physicians issued guideline recommendations for the use of opioids in the management of noncancer pain in 2017 (American Society of Interventional Pain Physicians (ASIPP) Guidelines).
 - iii. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-cancer Pain: American Pain Society and The Oregon Pain Treatment Guidelines (<https://www.oregonpainguidance.org/pain-treatment-guidelines>).
2. In addition to strategic inclusion through consideration of clinical guidelines, retrospective drug utilization review is also used to ensure that the most safe and cost-effective formulations are included in the formularies while ensuring that the patient has formulary alternatives sufficient for the appropriate management of his/her condition.
3. Opioids can be subject to the following Utilization Management (UM) tools:
 - i. **Quantity limits (QL)** – these limits can be based on prescribing information data, or if no ceiling dose is established by the manufacturer, the Pharmacy & Therapeutics (P&T) Committee approves the quantity limits.
 - ii. **Days' Supply Limits** - these limits can be based on prescribing information data, formulary or sub formulary where the opioid is included or recommendations from clinical guidelines or CMS. **By law, no refills are allowed for these prescription drugs.**
 - iii. Short-acting (SA) opioids are covered on the following formularies: Dental, Sub Physical, FEI (emergency), Physical, Ob-gyn and Oncology.
 - iv. Long Acting (LA) Opioids fentanyl (Duragesic) patches and Morphine CR (MS Contin) are covered under Oncology for cancer patients and Physical formulary without quantity limits.

B. Concurrent Drug Utilization Review (cDUR)

1. Supply Limits for Short Acting Opioid Naïve patients

- i. Edits will first screen for Cancer diagnosis code and will not initiate prescription limits if one is found.
- ii. A 3-7-days' supply limit edit **AND** maximum units per day for opioid-naïve patients will be set up as a hard safety edit.
 1. An opioid naïve patient is defined as a patient with no opioid prescription in their most recent sixty (60) days claim history.
 2. In most opioids, the adjudication system will allow **ONE (1)** fill within a 30-day timeframe.
- iii. When these edits are encountered, pharmacies must adjust the quantity to the limit permitted.
- iv. When these edits are encountered, pharmacies and prescribers should follow applicable federal or state dispensing laws for dispensing controlled substances.
- v. New supply limits will be implemented for short-acting opioids for opioid naïve patients for the treatment of acute pain.
- vi. These limits only affects new opioid users. Members already on a short-acting opioid treatment plan are not impacted.
- vii. Beneficiaries have the right to request a coverage determination to allow for extended use (beyond established supply limits) in some situations that must be justified by the prescribing physician.

A.H.H.

C. Cumulative Morphine Milligram Equivalent (MME) Doses

1. Opioid-containing drug products are identified within the processing and adjudication system, and the opioid content is determined in order to allow the processing system to calculate the Morphine Milligram Equivalent (MME) when the pharmacist submits an opioid prescription claim. In other words, the processing and adjudication system screens if the member exceed the soft or hard reject cumulative daily MME limit.
2. Members **NOT** new to therapy (have filled opioids in their most recent 60-day claims history) will be limited to a maximum of 89 morphine-milligram equivalents (MME) per day.
 - i. A soft reject is triggered when the cumulative daily MME is between 90 mg MME and 199 mg MME;
 1. As per CMS guidance for CY 2019, this reject can be resolved by the pharmacy using specific reasons codes only after consulting with the prescriber and documenting accordingly.
 2. Pharmacists must document such interventions with physicians for future audits.
 - ii. A hard reject is triggered when the cumulative daily MME is equal or over 200 mg MME;

1. This reject can only be resolved when the pharmacist, prescriber or beneficiary contacts the plan sponsor to request a coverage determination (PA).
3. This cumulative MME dose is a real-time safety alert at the time of dispensing, which is a proactive step to help ensure that providers and pharmacies are aware that potentially high-risk levels of opioids will be dispensed to their patients and to promote care coordination.
4. This Cumulative Morphine Milligram Equivalent (MME) Edit for Treatment Experienced Opioid Users will not apply to patients with Cancer.
5. This edit is not intended as a mean to implement a prescribing limit or apply additional clinical criteria for the use of opioids but instead to give physicians and pharmacists important additional information about their patients' opioid use, it is not intended to substitute the clinical judgement of the prescribers.

D. Additional Safety Edits

1. Opioid Potentiators - CMS Memorandum Dated March 16, 2018
 - i. CNS depressants are often misused or abused in conjunction with opioid analgesics to enhance euphoric effects.
 - ii. The FDA cited that the combination of opioids with CNS depressants has resulted in serious side effects, including slowed or difficult breathing, overdoses, and deaths.
 - iii. Some of the common CNS depressants may be utilized as opioid potentiators and clinicians should avoid prescribing concurrently with opioids whenever possible:
 1. Benzodiazepines – such as clonazepam and lorazepam are Schedule IV controlled substances with risk of misuse or abuse.
 2. Muscle Relaxants – such as carisoprodol, cyclobenzaprine, baclofen, tizanidine, chlorzoxazone, metholaxone commonly used to treat pain related to spasticity.
 3. Barbiturates including one of the most commonly prescribed Butalbital-Acetaminophen-Caffeine Tab (*Fioricet*)
 4. Sedative Hypnotics (benzodiazepine like hypnotics) – which includes zolpidem are also Schedule IV controlled substances with risk of misuse or abuse.
 5. Gabapentinoids – gabapentin, pregabalin which have multiple indications including the management of pain.
 6. Antihistamines – such as promethazine
 7. Antipsychotics as quetiapine have a history of misuse and abuse due to its sedating effects.
2. Duplicate therapy safety edits
 - i. Therapeutic Duplications: This safety edit in the pharmacy system looks at the member's current medications and identifies potential duplications to prevent members from taking more than one drug in the same drug class.
 1. The following duplicate therapy safety edits will be effective October 16, 2018:

A.H.H.

- a. Opioids indicated for the management of pain (not buprenorphine and buprenorphine/naloxone) - **Hard Reject** to avoid dispensing of two long or short acting opioids at the same time, pharmacies won't be able to use override codes at the point of service.
- b. Benzodiazepines - **Hard** rejects to avoid dispensing two benzos, pharmacies won't be able to use override codes at the point of service.
- c. Sedative Hypnotics - **Hard Reject** to avoid dispensing of two hypnotics at the same time, pharmacies won't be able to use override codes at the point of service.

3. Drug Interactions

- i. Drug-Drug Interactions: Checks the member's current medications and identifies potential instances where a member could be taking two drugs with an identified drug-interaction flag. A drug-drug interaction occurs when two medications taken together could cause an adverse event or affect the intended treatment of one of the medications.
- ii. The following drug interactions edits will be effective October 16, 2018.
 - 1. A **Soft Reject** will be triggered if the adjudication system finds that the patient is using any of the combinations below. This reject can be resolved by the pharmacist using specific reasons codes if, after using clinical judgment it determined the therapy as appropriate.
 - a. Opioids and Benzodiazepines
 - b. Opioids and Sedative Hypnotics
 - c. Opioids and Barbiturates
 - 2. A **Hard Reject** will be triggered if the adjudication system finds that the patient is using any of the buprenorphine combinations below indicated for the treatment of opioid dependence and will not allow dispensing of opioids to these patients. This reject cannot be resolved by the pharmacist using reasons codes.
 - a. Opioid and buprenorphine
 - b. Opioid and buprenorphine/naloxone to impede access to an opioid to patients on buprenorphine.

A.H.H.

4. Retrospective Opioid Utilization Reports

- i. ASES will follow CMS guidelines for CY 2019 to identify potential opioid overutilizers by monitoring Cumulative MME dose.
 - 1. Opioid-containing drug products (formulary and non-formulary) within the processing and adjudicating system are identified and the opioid content is determined.
 - 2. Beneficiaries with daily MME 90 or above will be reported to MCOs on a monthly basis.
 - 3. All the MCOs must provide appropriate case management aimed at coordinated care to these patients using more than 90MME daily.

5. Fraud, Waste, and Abuse (FWA) Programs

- i. Fraud, Waste and Abuse (FWA) Program is designed to promptly detect and investigate any instances of potential FWA at the pharmacy, prescriber and beneficiary level through utilization patterns involving:
 1. Top dispensed drugs;
 2. Top pharmacies that have increased dispensing rates;
 3. Top prescribers who prescribe most drugs;
 4. Top pharmacies that have increased brands dispensing rates;
 5. Top pharmacies that have increased controlled substances dispensing;
 6. Top members that have increased in drug utilization (including opioids);
 7. Identification of any opioids with three or more concurrent benzodiazepines in the same month;
 8. Among others.
- ii. This program also focuses on the reduction of inappropriate utilization, including minimizing the number of prescriptions filled and quantities per prescription, discontinuing therapies in certain drug classes, reducing dosages in senior members and detecting duplicate therapies. Therapy classes impacted include sedatives, opioids, diabetic medications and supplies, and migraine medications, among others. A component of the utilization management program targets potential abuse of medication (with special focus on controlled substances, such as opioids). Intervention letters to the physicians could, for example, be sent to notify them of possible "doctor or pharmacy shopping", on a case by case basis.
- iii. ASES' FWA Program identifies high-risk classified cases by analyzing the billing patterns of its pharmacy network through a series of reports such as those described above. Through this approach, we are able to identify, not only beneficiaries with egregious utilization patterns, but also pharmacies and prescribers.

E. ASES will continue updating this policy to implement additional clinical edit criteria to help ensure safer opioid utilization for MI Salud beneficiaries.

REVIEWED BY:

W. Poto

DATE:

18 / Sept / 2018

APPROVED BY:

[Signature]

DATE:

19 - sept - 2018



29 de abril de 2019

A: Aseguradoras, Compañías de Servicios de Salud Mental, Administrador del Beneficio de Farmacia, Farmacias, Grupos Médicos Primarios y Proveedores Participantes del Plan de Salud del Gobierno

Asunto: Registro de médicos en PDMP recomendado para proveedores de Vital

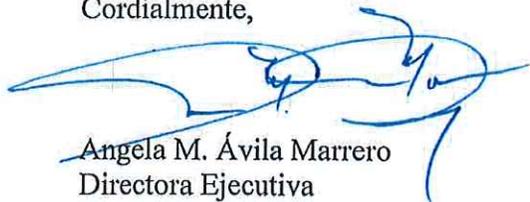
ASES está adoptando medidas para prevenir y combatir la crisis relacionada al mal uso de los opioides, así como de otras sustancias controladas en el Plan de Salud Vital. Es por esta razón que recomendamos que todos los médicos contratados por las cinco (5) aseguradoras que manejan el plan, **estén registrados en el Programa de Monitoreo de Medicamentos Recetados, PDMP** por sus siglas en inglés.

Para el cumplimiento de esta nueva recomendación, le ofrecemos la siguiente información:

- ❖ Registrarse en <https://puertorico.pmpaware.net/login>
- ❖ Previo a emitir una prescripción de medicamentos controlados, se recomienda entrar a la aplicación y verificar si al beneficiario le ha sido despachada una receta del medicamento controlado que planifica recetar, o de uno similar y el tiempo transcurrido desde esa receta previa. Basado en la data encontrada, su criterio médico y la necesidad de controlar el mal uso y abuso de estas sustancias en Puerto Rico, deberá recetar la cantidad mínima por los mínimos días necesarios para el tratamiento de ese paciente.

En la Carta Normativa CN18-0918 se explica en detalle la estrategia implementada el 16 de octubre de 2018, donde se limita las cantidades a dispensar en terapia de opiáceos. Le solicitamos encarecidamente que siga estas guías al momento de prescribir, y no recetar cantidades adicionales, a menos que sean necesarias y justificadas. También, dicha carta normativa explica el peligro del uso concomitante de opioides y potenciadores. Los invito a revisar dicho documento en <https://www.asespr.org/i/proveedores-2/comunicados/cartas-normativas/page/2/>

Cordialmente,



Ángela M. Ávila Marrero
Directora Ejecutiva

Anejo Carta Normativa 18-0918



PMP Aware™

With increasing death rates associated with unintentional overdose, it is more important than ever that healthcare institutions and pharmacies use the best tools available to identify, prevent, and manage substance use disorder.



APPRISS®
HEALTH



Prescription drug monitoring programs (PDMPs) are a recognized and useful tool, and 49 states, St. Louis County in Missouri, Washington D.C., Guam, and now Puerto Rico have all implemented a program. These programs collect controlled substance and other tracked medication dispensation information and store it in a database that prescribers, pharmacists and care-team members can access while caring for patients to make better-informed decisions about their care.

The Problem

According to the National Institute on Drug Abuse (NIDA), overdoses accounted for 52,404 U.S. deaths in 2015. Of these deaths, 33,091 involved an opioid, which equates to 90 Americans per day succumbing to this disease. NIDA's report on 2016 death statistics indicates a significant increase in overall overdose deaths, which is now estimated to be more than 64,000 a year, with 20,000 of those deaths related to illicit fentanyl. This data indicates that the overdose trend continues upward and continues to be most impacted by opioids. Many opioid overdose deaths are the result of nonmedical prescription pain reliever (NMPR) use, with 80% of recent heroin users reporting NMPR use within the past year.

Prescription drug monitoring programs are perhaps the best tool available to help guide clinician decision-making and awareness as it relates to prescription opioid use or misuse.

The Solution

Many of today's practicing clinicians view PDMPs as modern creations but the first PDMP was started in New York in 1918 and the longest continuously running state program began in 1939 in California. Today, there are 53 PDMPs in existence, including Puerto Rico.

The basic function of a PDMP is to act as an aggregator and disseminator of controlled substance dispensing information. Controlled substances such as opioids and benzodiazepines, among other drug types, represent the core of America's drug epidemic. Many PDMPs were started to help with clinical decision support with the intention that providers and pharmacists will more carefully consider and manage the risks and benefits of opioids and other controlled substances.

It is a best practice for healthcare providers and pharmacists to check the PDMP in certain circumstances. Some of the more obvious situations include: first prescriptions, prescriptions above a certain quantity, and at set intervals during chronic therapy. Beyond these situations, it is up to the provider or pharmacist to decide when a check of the PDMP might be appropriate. In a best case scenario, the PDMP should be used wherever and whenever it could inform providers and improve the care they deliver to patients.

With few exceptions, the drug problem cuts across all social, cultural, age, sex, and economic divisions. The problem has been classified as an epidemic and is likely the major health crisis of our time. An approach to maximizing PDMP effectiveness can be summarized as follows: Up front, every patient, every time.

1. UP FRONT | PDMP information should be available at the beginning of the patient encounter.

a. This approach allows the provider to incorporate the PDMP information into the History and Physical Exam which collectively are known as the H&P. The H&P is typically the first step in evaluating a patient and classical teaching is that history alone is up to 90% of the diagnosis.

As testing quality and availability have improved over the years, however, there has been some interest in challenging the importance of history and physical exam in making a correct diagnosis. Even in the modern era, though, an argument can be made that history is still the most powerful diagnostic tool, especially when combined with physical exam and basic testing.

b. Given that an H&P occurs early in the process, a query of the PDMP is the best method to guarantee availability when and where the information is most needed – early in the examination.

2. EVERY PATIENT | Make PDMP information available for every patient.

a. This approach recognizes that the drug epidemic cuts across all demographics. As an example, while it is generally accepted, some might argue that the very young can be excluded from a PDMP query. However, PDMP analyses do not back this up. New Mexico's PDMP published a report in 2013 showing that 5% of patients aged 5-14 years had received an opioid prescription in the last year. The FDA estimates that in 2015, about 4% of all patients receiving an opioid prescription were less than age 17, amounting to approximately 2.5 million individuals.

As another example, elderly patients account for nearly 20 million emergency department visits and more than 40 million opioid prescriptions per year in America. Opioids quintuple fall risk, cause urinary retention, cause constipation and nausea, alter mental status, and are arrhythmogenic. Ascertaining the potential role of opioids in these common complaints is essential to proper diagnosis. The PDMP can help.

3. EVERY TIME | Make PDMP information available every time the patient is seen.

a. The PDMP should be used to answer or substantiate the answer to several basic healthcare questions, some (or all) of which should be evaluated at every encounter.

- Is this patient opioid naive?
- Is this patient using controlled substances frequently or chronically?
- Is the patient's pattern or level of controlled substance use concerning?
- Is this patient at risk of overdose and in need of immediate help?

b. Given the prevalence of use (and misuse) of prescription drugs, all of the above questions are important for every provider to ascertain at every encounter, not just those encounters when a prescription may be contemplated. Detecting use, or misuse at the earliest possible intervention point is critical to minimizing adverse outcomes.

The PDMP is perfectly positioned to be at the center of Puerto Rico's solution to address the opioid epidemic by helping to identify, prevent, and manage substance use disorder.

About PMP Aware

Appriss Health provides the platform for 43 of the 53 prescription drug monitoring programs in the United States as well as Puerto Rico.

PDMPs are repositories of controlled substance dispensing information for real-time clinical decision support, critical insights and interventions for physicians, pharmacists and care team members.

PMP Aware, Appriss Health's PDMP platform, enables the assessment and management of clinical risk in order to positively impact patient safety and health outcomes.

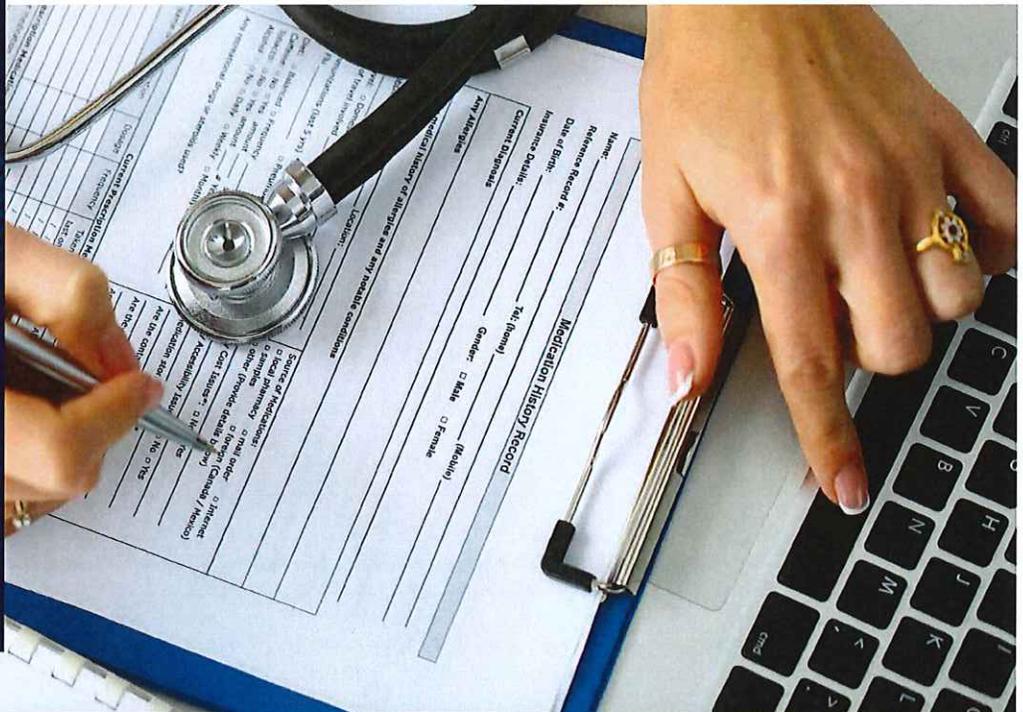
PMP Aware is a prescription drug monitoring program solution that provides prescribers and dispensers with accurate, real-time, information.

PMP Aware accepts prescription drug information from pharmacies, cleans and normalizes the data, reports errors back to pharmacies when/where necessary, and uses advanced algorithms and external data to match and consolidate patients. It then stores that information in a highly-available and scalable database and provides it to prescribers and pharmacists through a user-friendly website that is consistently updated and improved. The platform has 24/7/365 support.

By providing knowledge for good, Appriss Health is playing an instrumental role in partnering with prescribers and pharmacists across the U.S. and in Puerto Rico in successful prescription drug monitoring. With the information and power of PMP Aware, prescribers and dispensers are better able to make informed decisions and intervene earlier on behalf of their patients.

The Benefits

- PDMPs play an essential role in the effort to help control prescription drug misuse and abuse
- PDMPs improve clinical decision-making and can help to control prescription drug problems
- PDMPs track the distribution of narcotics and other prescriptions for controlled substances
- With accurate, real-time data, PDMPs can help to provide better clinical outcomes that can ultimately save lives
- Healthcare professionals, pharmacies, and patients can all benefit from the PDMP



Getting Started

Law number 70 of the 5th of August, 2017, "Ley de Vigilancia de Receta de Medicamentos Controlados" (Law for Monitoring the Prescription of Controlled Substances) established the "Programa de Monitoreo de Recetas de Medicamentos Controlados" (Prescription Monitoring Program for Controlled Substances) whose function will be to establish and maintain a system of electronic prescription monitoring of controlled substances dispensed in Puerto Rico.

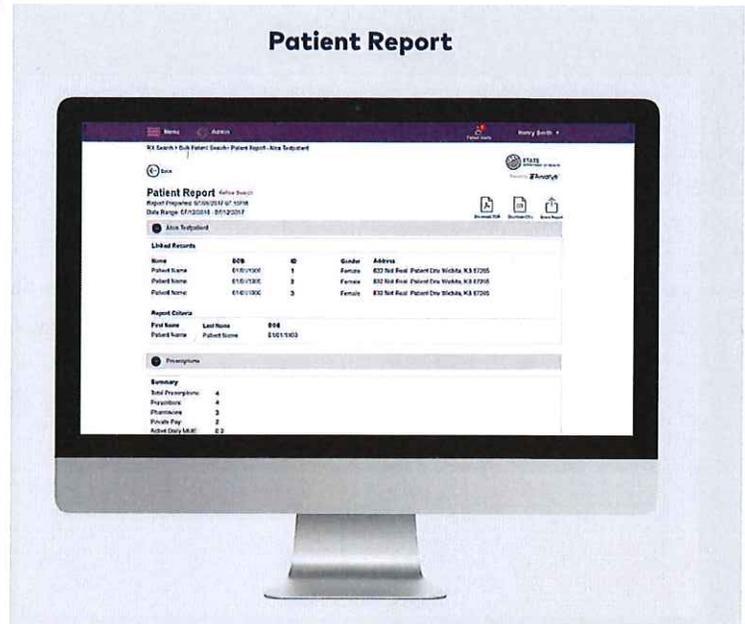
The Mental Health and Anti-Addiction Services Administration selected Appriss Health's PMP Aware platform to accomplish this.

The Puerto Rico Prescription Monitoring Program will begin to collect information regarding prescriptions of controlled substances on May 23, 2018. This information will be collected in the Appriss PMP Clearinghouse system.

On May 23, 2018 the Appriss PMP Clearinghouse system opened for data submissions. A "Puerto Rico Dispenser Guide" will be made available to all pharmacists and provides instructions for registration and submission, as well as the information required for submissions. A link to the Dispenser Guide can be found at <http://bit.ly/PRDispenserGuide>

It is recommended that pharmacy managers contact their pharmacy management software vendor or corporate office for additional guidance to report its pharmacy's controlled substance prescriptions. If you do not have a pharmacy management software or are not part of a corporate chain, please refer to the "Manual Submission" section of the "Puerto Rico Dispenser Guide" for guidance on uploading prescriptions.

Once your pharmacy is ready to begin reporting to PMP Clearinghouse, you will need to submit reports of all prescriptions for controlled substances that are dispensed on and after May 23, 2018.



For technical assistance with PMP Clearinghouse please contact the Appriss Helpdesk at 1-833-276-0091 (toll free). If you have any policy questions please contact the Mental Health and Anti-Addiction Services Administration at 1-787-763-7575, Ext. 1840.

About Appriss Health

Appriss Health provides the nation's most comprehensive platform for early identification, prevention, and management of substance use disorder (SUD). We provide state government agencies with the most advanced repository of controlled substance dispensing data and deliver real-time clinical decision support, critical insights, and interventions to physicians, pharmacists, and care team members. Our solutions help prescribers and dispensers assess and manage clinical risk by providing access to critical information at the point of care for hundreds of millions of patients encounters each year. Appriss Health provides the platform for PDMPs and access to PDMP data, non-PDMP data, analytics, tools, and resources from PDMPs, across state lines, and integrated within care team workflows. Sharing #knowledgeforgood, our solutions are improving patient safety and outcomes. For more information, please visit www.apprisshealth.com