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INSURANCE REGULATION
Docketed by:

OFFICE OF INSURANCE REGULATION

DAVID ALTMAIER
COMMISSIONER

IN THE MATTER OF:

CASE NO.: 268352-20

AETNA HEALTH PLAN OF FLORIDA
D/B/A/ COVENTRY HEALTH PLAN
AND AETNA LIFE INSURANCE COMPANY,

Petitioners.
_____/

FINAL ORDER

THIS CAUSE came on for consideration upon the filing of a Petition for Declaratory Statement ("Petition") by Aetna Health Plan of Florida d/b/a Coventry Health Plan and Aetna Life Insurance Company ("Petitioners"), with the Florida Office of Insurance Regulation ("Office") on August 14, 2020. The Office published notice of the Petition in the Florida Administrative Register at Volume 46, Number 171, and filed the Petition with the Joint Administrative Procedures Committee pursuant to and in compliance with Section 120.565(3), Florida Statutes[1], on September 1, 2020. No comments or requests to intervene were received and no hearing was held regarding the Petition. Having considered the Petition and relevant statutes and rules, the Office issues the following:

FINDINGS OF FACT

1. The Petition, attached hereto as Exhibit A, requests the Office issue a Declaratory Statement addressing the question of whether Section 627.64195, Florida Statutes, can be interpreted

[1] All references are to the 2020 Florida Statutes unless otherwise indicated.

to prohibit an issuer from requiring use of a non-abuse-deterrent opioid analgesic drug product only when an abuse-deterrent opioid analgesic drug product is available in the same formulation (i.e., can an issuer require an immediate-release opioid analgesic drug product without an abuse-deterrence labeling claim before authorizing an extended-release opioid analgesic drug product with an abuse-deterrence labeling claim, if an immediate-release opioid analgesic drug product with an abuse-deterrence labeling claim is not available).

2. In rendering this Final Order, the Office has relied on the statement of facts set forth in the Petition filed by Petitioners and, pursuant to Rule 28-105.003, Florida Administrative Code, has taken no position with regard to the validity of those facts.

3. Petitioners are issuers of health insurance policies in Florida.

4. Petitioners assert that they have a vested interest in how opioid analgesic drug products are prescribed to their policyholders and certificateholders, as such decisions can affect the health of these individuals.

5. Petitioners assert that guidance from the Centers for Disease Control and Prevention ("CDC")[2] places extended-release and long-acting opioid drug product forms within the same formulation or class.

6. Petitioners further assert that currently there are no abuse-deterrent immediate-release opioids analgesic drug products available on the U.S. market.

7. Petitioners point out that CDC guidelines suggest medical practitioners prescribe immediate-release opioid analgesic drug products to patients in most instances where acute, short-term pain management is the goal, leaving prescriptions for extended-release or long-acting opioid

[2] Petitioners cite *CDC Guidelines for Prescribing Opioids for Chronic Pain* (issued March 28, 2016) and other materials available at www.cdc.gov.

analgesic drug products for patients with severe, continuous pain for whom immediate-release opioid drug products are not appropriate.

8. Petitioners, again citing CDC guidelines, assert that abuse-deterrent labeling does not prevent abuse in every circumstance and does not, particularly in circumstances where opioids are taken orally, prevent the most common circumstance of abuse.

9. Petitioners' concern is that Section 627.64195, Florida Statutes, can be interpreted to prevent Petitioners from requiring the use of immediate-release opioid analgesics in acute, short-term pain management cases. They assert this may potentially harm patients who receive extended-release or long-acting opioids, a stronger opioid than may be medically necessary, and lead to opioid misuse and risk of overdose.

CONCLUSIONS OF LAW

10. Section 20.121(3)(a)1., Florida Statutes, provides, in part, that the Office shall be responsible for all activities concerning insurers and other risk bearing entities, including licensing, rates, policy forms, market conduct, and claims.

11. Section 624.01, Florida Statutes, provides that Chapters 624-632, 634, 635, 636, 641, 642, 648, and 651 constitute the "Florida Insurance Code."

12. The Office has jurisdiction over this matter pursuant to Section 20.121(3)(a)1., Florida Statutes; Section 120.565, Florida Statutes; and the Florida Insurance Code.

13. Section 120.565(3), Florida Statutes, requires an agency receiving a petition for declaratory statement to give notice of said filing in the next available issue of the Florida Administrative Register and transmit a copy to the Joint Administrative Procedures Committee.

14. Section 120.565(3), Florida Statutes, declares that the agency disposition of such a petition be a final agency action.

15. Section 120.569(2)(l), Florida Statutes, provides, in part, that a final order in a proceeding which affects substantial interests must be in writing and include findings of fact, if any, and conclusions of law separately stated.

16. Pursuant to Section 120.565(1), Florida Statutes, any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statute as it applies to the petitioner's particular set of circumstances.

17. It is well established that the purpose of a declaratory statement is to afford a petitioner the opportunity to seek an agency's position regarding the applicability of the agency's statutory provisions, orders, or rules in particular circumstances. *Adventist Health System/Sunbelt, Inc. v. Agency for Health Care Admin.,* 955 So. 2d 1173, 1176 (Fla. 1st DCA 2007) (citing *Chiles v. Div. of Elections,* 711 So. 2d 151, 154 (Fla. 1st DCA 1998)).

18. A declaratory statement can be used to avoid costly administrative litigation by informing the petitioner in advance as to the agency's views regarding the petitioner's contemplated conduct. *Agency for Health Care Admin.,* 955 So. 2d at 1176; *Chiles,* 711 So. 2d at 154; and *Nat'l Ass'n of Optometrists & Opticians v. Fla. Dep't of Health,* 922 So. 2d 1060, 1062 (Fla. 1st DCA 2006).

19. The Petition is filed for an allowed purpose, that is, to resolve a question or doubt concerning a statutory provision as it may apply to Petitioners' particular set of circumstances.

20. Petitioners possess the requisite interest and are the proper parties to request a declaratory statement under Section 120.565, Florida Statutes, and Chapter 28-105 et seq., Florida Administrative Code.

21. Section 627.64195, Florida Statutes, provides:

> (1) DEFINITIONS.—As used in this section, the term:
> (a) "Abuse-deterrent opioid analgesic drug product" means a brand or generic opioid analgesic drug product approved by the United States Food and Drug Administration

with an abuse-deterrence labeling claim that indicates the drug product is expected to deter abuse.

(b) "Opioid analgesic drug product" means a drug product in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions in immediate-release, extended-release, or long-acting form regardless of whether or not combined with other drug substances to form a single drug product or dosage form.

(2) COVERAGE REQUIREMENTS.—A health insurance policy that provides coverage for abuse-deterrent opioid analgesic drug products:

(a) May impose a prior authorization requirement for an abuse-deterrent opioid analgesic drug product only if the policy imposes the same prior authorization requirement for each opioid analgesic drug product without an abuse-deterrence labeling claim.

(b) May not require use of an opioid analgesic drug product without an abuse-deterrence labeling claim before authorizing the use of an abuse-deterrent opioid analgesic drug product.

22. The plain language of Section 627.64195, Florida Statutes, makes no distinction between immediate-release, extended-release, or long-acting opioids when defining "opioid analgesic drug product." Thus, subsection (2) of the statute makes no class distinctions when prohibiting issuers from treating abuse-deterrent opioids differently than non-abuse-deterrent opioids.

23. Further, Section 627.64195, Florida Statutes, would not prohibit a prescriber from following the CDC guidelines that Petitioners refer to in the petition. Should a medical practitioner determine that it is imperative to prescribe an extended-release or long-acting abuse-deterrent opioid analgesic instead of an immediate-release non-abuse-deterrent opioid analgesic, even for an acute pain management diagnosis, this statute would allow for such a medical decision. As written, giving room for such medical judgments would appear to be the intent of this statute.

ORDER

Based on the foregoing Findings of Facts and Conclusions of Law, it is hereby DECLARED THAT:

24. An issuer may not require use of an immediate-release opioid analgesic drug product without an abuse-deterrence labeling claim before authorizing the use of an abuse-deterrent opioid analgesic drug product.

DONE and ORDERED this 12 day of November, 2020.

David Altmaier

David Altmaier, Commissioner
Office of Insurance Regulation

NOTICE OF RIGHTS

Any party to these proceedings adversely affected by this Order is entitled to seek review within 30 days of the rendition of this Order, pursuant to Section 120.68, Florida Statutes, and Rule 9.190, Florida Rules of Appellate Procedure. Review proceedings must be instituted by filling a petition or notice of appeal with the Agency Clerk:

Anoush Arakalian Brangaccio, General Counsel
Florida Office of Insurance Regulation
200 East Gaines Street
Suite 647E
Tallahassee, Florida 32399

Filing with the Agency Clerk may be accomplished via U.S. Mail or hand delivery. The filing date for a document, no matter the method of transmission, shall be the date the Office receives the document. Any document received after 5:00 p.m. shall be filed as of 8:00 a.m. on the next regular business day.

A copy of the petition or notice of appeal must also be filed with the appropriate district court of appeal within 30 days of the rendition of this Order.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy the foregoing Final Order was sent by U.S. Mail, this 12 day of November, 2020 to:

D. Bruce Platt
Akerman LLP
201 East Park Avenue, Suite 300
Tallahassee, FL 32301

Thomas A. Range
Akerman LLP
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/s/
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OFFICE OF INSURANCE REGULATION
AUG 14 2020
LEGAL SERVICES OFFICE

BEFORE THE STATE OF FLORIDA
OFFICE OF INSURANCE REGULATION

In Re:
Aetna Health Inc. d/b/a Coventry Health Plan of Florida
and Aetna Life Insurance Company

Petition for Declaratory Statement
before the Florida Office of Insurance Regulation
_____/

Petition for Declaratory Statement

Aetna Health Inc. d/b/a Coventry Health Plan of Florida, Inc. and Aetna Life Insurance Company (collectively, "Aetna") file this Petition for Declaratory Statement pursuant to section 120.565, Florida Statutes, and Rule 28-105.002, FAC. In support, Aetna states:

1. Aetna requests that the Office of Insurance Regulation declare that section 627.64195, Florida Statutes, be interpreted to prohibit an issuer from requiring the use of an opioid analgesic drug product without an abuse-deterrence labeling claim only when an opioid analgesic drug product with an abuse-deterrence claim is available in the same formulation (*i.e.*, section 627.64195 should be interpreted to allow an issuer to require an immediate-release, opioid analgesic drug product without an abuse-deterrence labeling claim, before it authorizes an extended-release, opioid analgesic drug product with an abuse-deterrence labeling claim, if an immediate-release, opioid analgesic drug product with an abuse-deterrence labeling claim is not available).

2. Aetna's contact information is 151 Farmington Avenue, Hartford, Connecticut, 06151; email – Tara.Danforth@CVSHealth.com; phone – 480-314-8834; and fax – 480-314-6378. For purposes of this petition, Aetna should be contacted through counsel: Bruce D. Platt and Thomas A. Range, Akerman LLP, 201 East Park Avenue, Suite 300, Tallahassee, FL 32301;

bruce.platt@akerman.com and tom.range@akerman.com; phone – 850-224-9634; and fax – 850-222-0103.

Background on Abuse-Deterrent Opioid Analgesic Drug Product Issue

3. During the 2016 Legislative Session, the Florida Legislature passed Senate Bill 422, which was approved by the governor and later codified as section 627.64195.

4. Section 627.64195 was adopted to "provide patients with greater access to abuse-deterrent opioid analgesic drug products, which is expected to reduce opioid drug misuse, abuse, and diversion."[1]

5. In section 627.64195, the Florida Legislature recognizes three distinct formulations of opioid analgesic drug products ("Opioids"): immediate-release, extended-release, and long-acting. However, extended-release and long-acting are clinically treated as being in the same category.[2] Thus, from a clinical standpoint, there are essentially two types of formulations for Opioids: immediate-release Opioids ("IR Opioids") and extended-release/long-acting Opioids ("ER/LA Opioids").

6. The United States Center for Disease Control ("CDC") Guideline for Prescribing Opioids for Chronic Pain ("CDC Guideline")[3] states:

- "When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids."

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[1] *Bill Analysis and Fiscal Impact Statement*, Page 5, Staff of the Committee on Appropriations, February 17. 2016.

[2] For example, the CDC categorizes the formulations of Opioids as follows: (1) Extended-release/long-acting (ER/LA) opioids – Slower-acting medication with a longer duration of pain-relieving action; and (2) Immediate-release opioids – Faster-acting medication with a shorter duration of pain-relieving action. *See* https://www.cdc.gov/drugoverdose/opioids/terms.html.

[3] *See CDC Guideline for Prescribing Opioids for Chronic Pain* (issued March 18, 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1er.htm.

- "Experts agreed that for patients not already receiving opioids, clinicians should not initiate opioid treatment with ER/LA opioids and should not prescribe ER/LA opioids for intermittent use. ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week."
- "Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed."

7. No abuse-deterrent, IR Opioids are currently available in the United States.[4] If section 627.64195 is interpreted to require the authorization of an abuse-deterrent ER/LA Opioid before an issuer is allowed to require the use of a non-abuse-deterrent IR Opioid, issuers will be required to authorize coverage of ER opioids for opioid-naïve members – in direct contravention of the CDC Guideline and accepted clinical standards for reducing opioid misuse and risk of overdose.

[4] The FDA has approved only one abuse-deterrent IR Opioid, RoxyBond (*see* https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics), but its manufacturer canceled its licensing agreement in the United States (*see* https://www.fiercepharma.com/pharma/daiichi-sankyo-exits-u-s-pain-market-amid-oncology-pivot-opioid-scrutiny).

The Requested Interpretation is Consistent with the Statute and Allows Compliance with the CDC Guideline and Accepted Clinical Standards

8. Section 627.64195, F.S., defines "opioid analgesic drug product" as "a drug product in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions **in immediate-release, extended-release, or long-acting form** regardless of whether or not combined with other drug substances to form a single drug product or dosage form" (emphasis added).

9. Aetna believes that the Legislature specifically included a reference to immediate-release, extended-release, and long-acting forms because the Legislature intended that these should be treated as separate and distinct opioid analgesic drug products consistent with the CDC Guideline and accepted clinical standards.[5] In other words, because each Opioid formulation (IR and ER/LA) carries its own separate risks and benefits, each formulation should be likewise treated separately. If the Legislature had not intended for the formulations to be treated differently, there was no need to list them in the statute. Because they are separately identified in the statute, and

[5] For example, a peer-reviewed study recommended the avoidance of long-acting opioids in the acute setting and noted that, although immediate-release opioids are prescribed at a significantly higher rate than extended-release options, extended-release medications still result in a 4.6-fold higher abuse rate and a 6.1 times increased diversion potential. *See* "The Orthopaedic Trauma Association Musculoskeletal Pain Task Force Clinical Practice Guidelines for Pain Management in Acute Musculoskeletal Injury" (Joseph R. Hsu, MD*; Hassan Mir, MD; Meghan K. Wally, MSPH*; Rachel B. Seymour, PhD), JOURNAL OF ORTHOPAEDIC TRAUMA (May 2019). Additionally, UpToDate, a widely respected reference source that summarizes current medical literature and makes clinical recommendations, also agrees with the CDC Guideline and recommends that IR Opioids rather than ER/LA Opioids should be prescribed exclusively for treatment of acute pain in opioid naïve patients. *See* "Prescription of opioids for acute pain in opioid naïve patients" (Carlos A Pino, MD; Melissa Covington, MD; Sarah E Wakeman, MD), UpToDate (last updated June 8, 2020) (noting that unintentional overdose may be more likely if opioid therapy is initiated with long-acting opioids).

because the Legislature is presumed to have listed them separately for a reason,[6] this supports Aetna's requested interpretation that each formulation be treated separately.

10. This requested interpretation is consistent with the Legislature's intent when enacting section 627.64195 as a means to reduce "opioid drug misuse, abuse, and diversion." Likewise, this interpretation is also consistent with accepted clinical standards that IR Opioids are the most clinically appropriate treatment option for opioid-naïve patients because of the lower potential for misuse and overdose. Moreover, as the CDC Guideline recognizes, an abuse-deterrent formulation still carries a risk of abuse (emphasis added and footnote omitted):

> Abuse-deterrent technologies have been employed to prevent manipulation intended to defeat extended-release properties of ER/LA opioids and to prevent opioid use by unintended routes of administration, such as injection of oral opioids. As indicated in FDA guidance for industry on evaluation and labeling of abuse-deterrent opioids, although abuse-deterrent technologies are expected to make manipulation of opioids more difficult or less rewarding, they do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes. **The "abuse-deterrent" label does not indicate that there is no risk for abuse.** No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. **In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake.** Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

The Statute on Which the Declaratory Statement is Sought

11. The statute at issue is section 627.64195, F.S., which reads:

(1) DEFINITIONS.—As used in this section, the term:

(a) "Abuse-deterrent opioid analgesic drug product" means a brand or generic opioid analgesic drug product approved by the United States Food and Drug

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[6] *See Metro. Cas. Ins. Co. v. Tepper*, 2 So. 3d 209, 215 (Fla. 2009) (requiring courts to avoid interpreting a statute in a way that would render part of the statute meaningless and noting that statutory language must not be "construed as superfluous if a reasonable construction exists that gives effect to all words") (cleaned up).

Administration with an abuse-deterrence labeling claim that indicates the drug product is expected to deter abuse.

(b) "Opioid analgesic drug product" means a drug product in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions in immediate-release, extended-release, or long-acting form regardless of whether or not combined with other drug substances to form a single drug product or dosage form.

(2) COVERAGE REQUIREMENTS.—A health insurance policy that provides coverage for abuse-deterrent opioid analgesic drug products:

(a) May impose a prior authorization requirement for an abuse-deterrent opioid analgesic drug product only if the policy imposes the same prior authorization requirement for each opioid analgesic drug product without an abuse-deterrence labeling claim.

(b) May not require use of an opioid analgesic drug product without an abuse-deterrence labeling claim before authorizing the use of an abuse-deterrent opioid analgesic drug product.

Decription of how section 627.64195, Florida Statutes, Substantially Affects Aetna

12. Aetna has a vested interest in the health of its members. Requiring Aetna to authorize higher risk ER/LA Opioids, when the CDC Guideline and accepted clinical standards both state that IR Opioids are more appropriate, potentially endangers the health of persons who receive coverage through Aetna. For individuals initiating opioid treatment, ER/LA Opioids have

a higher risk of overdose than IR Opioids.[7] According to the CDC Guideline and FDA labeling, ER/LA Opioids have serious risks and should be reserved for "'management of pain severe enough to require daily, around-the-clock, long-term opioid treatment' when 'alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain' and not used as 'as needed' pain relievers."[8] Interpreting 627.64195, F.S. to prohibit health insurance issuers from requiring use of an IR Opioid formulation prior to authorizing an ER/LA Opioid formulation removes a tool that Aetna and other issuers use to help protect the health, safety, and welfare of their members and guard against opioid misuse, abuse, and overdose.

WHEREFORE, Aetna requests that the Office issue a Final Order determining that section 627.64195, Florida Statutes, should be interpreted to prohibit an issuer from requiring use of a non-abuse-deterrent opioid analgesic drug product only when an abuse-deterrent opioid analgesic drug product is available in the same formulation.

Respectfully submitted on August 14, 2020.

s/ Bruce D. Platt
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[7] *See* CDC Guideline, *citing* "Prescription opioid duration of action and the risk of unintentional overdose among patients receiving opioid therapy" (Miller M, Barber CW, Leatherman S, *et al.*), JAMA INTERN. MED. 2015;175:608–15.

[8] *See* CDC Guideline, *citing* "Goal of label changes: better prescribing, safer use of opioids," Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2013. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm367660.htm.

Certificate of Service

I hereby certify that this Petition for Declaratory Statement was filed via email with the Agency Clerk, Anoush Brangaccio (Anoush.Brangaccio@floir.com), Florida Office of Insurance Regulation, 200 East Gaines Street, Suite 647E, Tallahassee, FL 32399-4206 and a courtesy copy sent via email to Sarah Berner (Sarah.Berner@floir.com) on August 14, 2020.

s/ Bruce D. Platt