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Insys Litigation Documents – Insurance Reimbursement Center (IRC)

Summary and Sample Documents Explained:

Insurance companies use <u>utilization management</u> tools such as <u>prior authorization (PA)</u> to improve drug safety and value, yet such tools may decrease prescription drug sales. As part of the prior authorization process, health insurers require patients to meet certain criteria before covering <u>Transmucosal Immediate-Release Fentanyl (TIRF)</u> medicines like Subsys, including that the patient has a diagnosis of cancer, is opioid tolerant, and has tried alternative medications. Insys launched an in-house Reimbursement Center to evade PA policies governing their products.

Insys Reimbursement Center (IRC) employees used protected Patient Health Information (PHI) that they were not legally permitted to access. When IRC staff called insurance companies to obtain approval for Subsys prescriptions, Insys employees misrepresented staff as working for physicians' offices and were intentionally vague about the patients' medical conditions, in an attempt to make the insurers believe that patients had an approved diagnosis of "breakthrough" cancer pain when they did not.

Sample Documents:

Document Title: FW: Pilot Program for Prior Authorizations **OIDA ID:** https://idl.ucsf.edu/opioids/docs/#id=ftmc0265

Date: 2012-11

Description: This email chain between the IRC's Mike Gurry and members of the Insys sales force (Alec Burlakoff, Sunrise Lee, and Brett Szymanski) provides insight into the physicians who were selected for the pilot program. Here, Gurry asks Szymanski if one of the physicians in his sales region might be a good inclusion in the pilot, based on the fact that the physician had "written a lot of SUBSYS." (Although they misspell his name, the suggested doctor appears to be Gavin Awerbuch, who later was sentenced to 32 months in prison for his involvement with Insys kickbacks.)

Document Title: Patient Starter Kit – packaging and brochures; Volume 08 001e.pdf

OIDA ID: https://www.idl.ucsf.edu/opioids/docs/#id=hyyc0233

Date: 2014

Description: Photographs document the <u>"starter kit"</u> given to prescribers and patients, which included usage instructions, a practice spray device, medication guide, dosing instructions, and forms for the Insurance Reimbursement Center and the TIRF REMS (Risk Evaluation and Mitigation Strategy) programs.

Document Title: InSys Therapeutics, Inc.; DEC 2014 DRONABINOL ID SC MEETING

FINAL.PPTX

OIDA ID: https://www.idl.ucsf.edu/opioids/docs/#id=sqyc0233

Date: 2014-12

Description: Included in this slide deck for a presentation to Insys's Physician Advisory Board is a slide about the Reimbursement Center, noting that Insys's "dedicated team of PA specialist [sic] will assist with logistics throughout the PA process...."

Document Title: BUSINESS RELATIONSHIP MANAGER.PDF **OIDA ID:** https://www.idl.ucsf.edu/opioids/docs/#id=rnng0233

Date: 2014-07

Description: This job description outlines expectations for a Business Relationship Manager, a position within the Reimbursement Center that worked hand-in-hand with sales representatives, physician offices, and pharmacies.

Document Title: GENERIC IRC EMAIL/PHONE # **OIDA ID:** https://idl.ucsf.edu/opioids/docs/#id=kqjn0265

Date: 2013-10

Description: Angel Alarcon, IRC manager, emails Maury Rice, IT director, asking for a generic phone number because "some insurance plans/pharmacies/patients will not accept calls from blocked numbers." (The IRC's number was blocked so insurance payors would not see it was an Insys department.) Alarcon also asks whether Rice can create a "generic email" for filling out PA appeals online "that doesn't link us to Insys, the manufacturer."

Document Title: INSYS THERAPUTICS [sic] FORMS **OIDA ID:** https://idl.ucsf.edu/opioids/docs/#id=qgyw0269

Date: 2016-02

Description: Reimbursement Center staff recorded call notes about prior authorization appeal efforts made for specific patients. Of note here are rationales that the IRC staff offered when appealing PAs, as well as insurers' "Reason(s) for Denial" and that a "spiel" was used.

Document Title: InSys Therapeutics, Inc.

OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=jtmc0265

Date: 2015-03

Description: The IRC built up a knowledge base of each insurer's "requirements" for approving prior authorizations— the rationales by which they would approve payment for a patient's Subsys prescription. These PowerPoint slides chart each insurer's requirements, such as "difficulty swallowing" pill formulations, "inadequate analgesic effect" of other drugs, or the patient having found a generic drug "not reliable."

Document Title: XXXXXXXXXXXX – APPEAL.PDF **OIDA ID:** https://idl.ucsf.edu/opioids/docs/#id=qawf0269

Date: 2013-02

Description: Dr. <u>Gavin Awerbuch</u> wrote this letter of appeal arguing that his patient needs Subsys for breakthrough pain related to "whiplash injury and... degenerative disc syndrome." The only indication for Subsys approved by the FDA was for breakthrough cancer pain, that is, flare-ups of cancer-related pain that are tolerant to other opioids the patient takes.

Document Title: KEY PHRASES GRID 04242015 (2).XLSX **OIDA ID:** https://idl.ucsf.edu/opioids/docs/#id=jgwf0269

Date: 2015-04

Description: The Reimbursement Center developed technically honest "key phrases" to persuade payors to authorize Subsys prescriptions. One of these, internally referred to as "the spiel," or "verbatim statement," implies that Subsys is being prescribed for breakthrough cancer pain: "The physician is aware that the medication is intended for the management of

breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable)." IRC staff are advised not to pause while reading the statement to an insurer.

Document Title: Recap of today's meeting

OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=zsmc0265

Date: 2014-12

Description: Liz Gurrieri, IRC manager, emails a meeting summary to her team, including a list of "plans that we cannot call on at this time or that are tracking us," with a cautionary note that "Emblem Health is starting to catch on."

Document Title: think we should delete

OIDA ID: https://idl.ucsf.edu/opioids/docs/#id=ysmc0265

Date: 2015-05

Description: Gurrieri emails <u>Alyssa Fulton</u>, supervisor for reimbursement services, with attached documents that include the "spiel" verbiage, as well as specific responses to give to various insurers to successfully get authorizations approved. Guerrieri asks, "Think we should delete these?" Fulton's response: "OMG DELETE!"

Additional Documents		
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