HEALTHCARE PAYER STRATEGIES TO REDUCE THE HARMS OF OPIOIDS

The Healthcare Fraud Prevention Partnership's Commitment to the Management of Opioid Misuse and Opioid Use Disorder

WHITE PAPER
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healthcare fraud prevention partnership

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EXECUTIVE SUMMARY

OVERVIEW

Prescription opioid misuse and opioid use disorder (OUD) are significant and growing public health problems in the United States (U.S.) that impact stakeholders across the healthcare sector, including private, employer-sponsored, and public health plans.(1-4)[1] Healthcare payers (herein, payers), employer organizations, and law enforcement all have strong motivations to combat the inappropriate prescribing of opioids to improve patient health and reduce expenditures for medically unnecessary services and therapies. These are large-scale problems for which payers play a critical role in reducing fraud, waste, and abuse while ensuring access to medically necessary therapies.

Payers can help to combat the opioid crisis by identifying and sharing strategies, such as reimbursement and coverage policies, conditions for provider plan participation, and dissemination of information to a variety of audiences, to address the large-ranging issues that lead to fraud, waste, and abuse in the healthcare system. Such interventions are particularly suited to payers due to their relationships with providers of healthcare services, pharmacies, insured patients, employers, and law enforcement (in cases where potential fraud is identified). Payers collect and administer a large amount of healthcare information that can be used to identify and intervene on behalf of patients at risk of opioid-related harm, as well as to target fraud, waste, and abuse in opioid prescribing.

[1] Though this paper focuses on prescription opioid misuse, the issues and strategies discussed herein may also be applicable to non-prescription opioids, such as heroin.

THE HEALTHCARE FRAUD PREVENTION PARTNERSHIP'S APPROACHES AND PRIORITY ACTIONS TO COMBAT OPIOID MISUSE AND OPIOID USE DISORDER

The Healthcare Fraud Prevention Partnership (HFPP) is a voluntary, public-private partnership between the federal government, state agencies, law enforcement, private health insurance plans, employer organizations, and healthcare anti-fraud associations to identify and reduce fraud, waste, and abuse across the healthcare sector.(5) HFPP partners regularly collaborate, share information and data, and conduct cross-payer studies to achieve these objectives. Given the HFPP's broad membership, encompassing a variety of players that are interested and involved in the detection of fraud, waste, and abuse in the healthcare system, it is positioned to examine the opioid crisis and develop key recommendations from a unique perspective.

Several HFPP partners have taken a particular interest in the further study and consideration of ways in which payers can influence and impact prescription opioid misuse in the U.S. and dedicated themselves as Partner Champions toward this effort. These HFPP Partner Champions have committed themselves to the creation of an HFPP White Paper that describes the best practices for serious consideration by all healthcare payers and other relevant stakeholders to effectively address and minimize the harms of opioids while ensuring access to medically-necessary therapies and reducing fraud, waste, and abuse (see page 3 for the list of HFPP Opioids White Paper Partner Champions).

CREATION OF THE HFPP APPROACHES RELATED TO PRESCRIPTION OPIOID MISUSE

The HFPP Approaches related to prescription opioid misuse and OUD were developed to provide the guiding principles for the HFPP's recommended actions. The HFPP Approaches reflect the individual input of the HFPP partners regarding their priorities and experiences in dealing with opioid misuse across their patient populations and coverage areas. Input was provided by multiple partners, modifications were made to address this input, and revisions were made until all participating partners were satisfied that the final language reflected what they believe are the HFPP Approaches related to prescription opioid misuse and OUD.

In October 2016, the HFPP convened a special session of its membership for the purpose of discussing what the HFPP can do in regards to the increasing problems of opioid misuse (taking opioids in a way other than prescribed) and OUD (the severest of which is often referred to as addiction and includes symptoms such as continued use in the face of negative consequences, drug cravings, development of tolerance, and an inability to reduce consumption). During this session, the Partner Champions articulated the HFPP's approaches with respect to the management of prescription opioid fraud, waste, and abuse and identified feasible strategies representing best practices. Specifically, the Partner Champions identified three core approaches reflecting their mission. The approaches served as guiding principles for the HFPP's recommended actions for addressing prescription opioid misuse and OUD, all of which should be strongly considered by all payers and other relevant stakeholders in the U.S. This framework was developed, in part, on the U.S. Department of Health and Human Services (HHS) and Centers for Medicare & Medicaid Services (CMS) priority areas for addressing opioid use (please see Appendix A for more information).(6, 7)

HFPP APPROACH 1:
Share resources, policies, and practices that connect patients to care that is best suited to their needs and achieves optimal outcomes, ultimately reducing opportunities for fraud, waste, and abuse related to opioids.

Patient health and well-being are central to the HFPP's mission. In this vein, the HFPP supports sharing best practices that encourage appropriate care and prescribing practices, reduce barriers to resources that protect patients receiving medical-necessary opioid therapy from the harms of opioids, and minimize the potential for fraud, waste, and abuse in the healthcare system.

HFPP APPROACH 2:
Identify and mitigate potentially fraudulent, abusive, or wasteful activities related to opioids.

This approach aligns with an important part of the HFPP's mission: the identification and elimination of fraud, waste, and abuse of the healthcare system. The HFPP is committed to addressing fraud, waste, and abuse associated with opioid misuse and OUD as well as coordinating and cooperating with law enforcement and other relevant governmental or regulatory bodies to these issues.

HFPP APPROACH 3:
Engage in innovative studies and information sharing techniques within the HFPP to identify and share effective opioid misuse and OUD mitigation strategies.

The HFPP supports the creation and dissemination of new information related to best practices in combatting opioid misuse and OUD. The HFPP data resources are unparalleled in the U.S., as no comparable cross-payer collection of timely healthcare payment data exists elsewhere. At the same time, knowledge gaps continue to exist regarding the most effective strategies to reduce inappropriate opioid prescriptions, promote recovery from OUD, and increase the use of opioid alternative therapies for pain management. Here, the HFPP states its commitment to using its considerable data resources to address these questions.

HFPP PRIORITY ACTIONS

To put its approaches into practice, the HFPP has identified five specific actions that should be strongly considered for implementation by all payers as soon as possible. The list below is not organized by priority, is not exhaustive, and should not preclude other meaningful actions. Rather, these actions are based on specific strategies identified by HFPP partners that are supported by evidence. These actions represent steps that payers can execute within their own organizations and that other key stakeholders, such as law enforcement and employer organizations, can promote and support. In accordance with this premise, the HFPP Opioid White Paper Partner Champions are also committed to strongly consider each of the action steps below and implement or promote each step within their own organizations.

1. **Train providers on the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain.** The HFPP strongly encourages payers to consider communication and incentive models that will result in providers achieving knowledge of and adherence to the CDC Guideline for Prescribing Opioids for Chronic Pain.(1) This guideline exists to assure the appropriate and safe utilization of prescription opioids; however, they will only achieve this result when providers are aware of their content and implement their recommendations.

2. **Promote access to and usage of Medication-Assisted Treatment (MAT).** The HFPP strongly encourages the promotion of MAT services as part of a complete treatment program through reimbursement policy and provider recruitment and education for patients who misuse opioids or have an OUD. MAT, in combination with behavioral therapy, is more effective in treating OUDs than behavioral therapy alone, and its use should be widely promoted and reimbursed.

3. **Promote the availability of naloxone.** The HFPP supports reducing unnecessary barriers to the availability of, and reimbursement for, naloxone. The HFPP strongly encourages the promotion of naloxone availability for patients at risk for opioid overdose to prevent the unintended and catastrophic consequences of ineffective management or misuse of prescription opioids. Promoting the availability of naloxone represents a responsible and ethical response to a significant public health crisis while also ensuring access to needed therapies to achieve positive patient outcomes.

4. **Encourage the use of data to identify fraudulent, wasteful, or abusive practices associated with opioids in order to target corrective actions.** The HFPP strongly encourages the use of singular and cross-payer data to identify patients at risk of opioid misuse and OUD, to prevent non-medical use of prescription opioids and drug diversion schemes, and to act upon those findings. Data systems can be used to identify at-risk patients and aberrant or suspicious opioid prescribing or use trends. This information can help direct investigative resources and appropriate interventions. Participation in studies using cross-payer data, such as through the HFPP, is recommended as these studies can be particularly helpful in identifying fraudulent or wasteful activities across organizations and initiating actions based upon these findings.

5. **Identify and disseminate effective practices across the healthcare sector.** The HFPP strongly encourages collaborative efforts to develop and widely disseminate effective strategies to identify: patients at risk of opioid misuse or OUD, providers whose opioid prescribing patterns fail to comply with quality indicators (such as the CDC Guideline for Prescribing Opioids for Chronic Pain), and methods that are particularly effective at preventing or treating OUD. Whenever possible, these strategies should include ways to measure their effectiveness in achieving the intended goals.

Through coordinated action, payers, including members of the HFPP, have the opportunity to dramatically influence and reduce opioid misuse in the U.S. Simple actions performed systematically across a large group of stakeholders can considerably decrease the toll of prescription opioid misuse and OUD in the U.S.

INTRODUCTION

PRESCRIPTION OPIOID MISUSE AND OPIOID USE DISORDER

The effects of opioid misuse and OUD have conspired to create an unparalleled public health crisis in the U.S., affecting millions of citizens and challenging a healthcare system that is committed to turning the tide of opioid misuse and OUD while ensuring that patients receive the treatments they need.(8) Healthcare payers play a monumental role in the execution of a healthy and viable healthcare system, including the identification and sharing of strategies to address the large-ranging issues that lead to fraud, waste, and abuse in the healthcare system, such as the impacts of opioid misuse and OUD. The HFPP is a voluntary, public-private partnership between the federal government, state agencies, law enforcement, private health insurance plans, employer organizations, and healthcare anti-fraud associations to identify and reduce fraud, waste, and abuse across the healthcare sector. This paper is a collection of proven tools that healthcare payers can and should utilize, when possible, to address the opioid crisis.

The CDC estimates that prescription opioid misuse, OUD, and opioid overdose cost the U.S. economy over $78 billion in 2013 in the form of higher healthcare and substance use disorder treatment costs, excess criminal justice costs, and productivity losses borne by employers.(9) Further, prescription opioids are often fraudulently obtained for resale on the black market.(10) For example, among a sample of 5,420 urine test samples of commercially insured patients prescribed opioid analgesics by their primary care provider to manage chronic pain, nearly 13 percent tested negative for any opioid consumption, a result which could suggest prescription diversion, although these patients may simply be non-adherent.(11)

The wide availability of prescription opioids has likely contributed to increases in misuse of these medications and OUDs.(12) Over the last 20 years, several factors have vastly increased the supply of opioid analgesics in the U.S.(13) These factors include, but are not limited to the introduction of newly-branded opioid formulations with high misuse potential, relaxed opioid prescribing patterns by some providers, patient perceptions of prescription opioids being safer than illicit drugs, expanded payer reimbursement for opioid prescriptions, intensified opioid drug-seeking by individuals with an opioid misuse history or OUD, and the fraudulent acquisition and diversion of opioids to the black market for profitable resale.(14-18) The number of opioid prescriptions supplied by U.S. retail pharmacies increased from 76 million in 1991 to 219 million in 2011, the year that the CDC first released guidance on opioid prescribing.(1,19, 20)

The prevalence of non-medical use of prescription opioids among Americans ages 12 and older has also increased over time. Based on the National Survey on Drug Use and Health, the percentage of Americans who used a prescription opioid for non-medical reasons at least one time in the last year grew from 3.7 percent in 2001 to 4.5 percent in 2014 (an estimated 10.4 million people).(21, 22)

Adverse side effects from opioid misuse strongly correspond with this increase in prescriptions. More than 165,000 Americans died from a prescription opioid overdose between 1999 and 2014.(23) In 2015, an estimated 17,536 overdose deaths were attributed to prescription opioids (other than non-methadone synthetics). Opioid overdoses are not limited to those individuals who fraudulently obtain prescriptions.(24) For example, a CDC report from 2012 indicated that approximately 60 percent of total prescription opioid overdoses occurred among patients who were prescribed opioids by a single physician, with the remaining 40 percent attributable to patients who received opioid prescriptions from multiple doctors.(25) Approximately 20 percent of prescription opioid overdoses occurred among patients prescribed less than a morphine equivalent dose of 100 milligrams per day from a single provider.(25) Rates of prescription opioid overdose deaths have also been shown to track closely with the rates of opioid prescribing at the state level.(26)

It is important to keep in mind that millions of providers prescribe opioids and many patients take them as prescribed by their doctor, experience limited adverse effects, and realize health benefits in the form of reduced pain and suffering. However, to overcome the problems of prescription opioid misuse, it is also vital to understand that provider prescribing practices and patient drug seeking behavior can exacerbate the development and persistence of OUD. Providers may write prescriptions without assessing their patient's risk for misuse, prescribe opioid analgesics for minor pain, prescribe a greater medication quantity or dose than warranted by the patient's medical indication, or provide opioids fraudulently with the knowledge they are likely to be misused.(14, 27-30) Patients may exaggerate or falsify symptoms to obtain opioid prescriptions, seek prescriptions from multiple physicians, forge prescriptions, or obtain prescriptions for resale on the black market.(14) Improper utilization of healthcare services may result in or intensify opioid misuse and OUD, impacting patients and the healthcare system alike. In short, these are large-scale problems for which payers play a critical role in reducing fraud, waste, and abuse.

THE ROLE OF PAYERS

Over the past decade, payers across the U.S. have developed a large number of strategies to control and mitigate the consequences of the opioid crisis and the associated fraud, waste, and abuse. Payers maintain unique relationships with patients, medical providers, pharmacies, employers, and law enforcement (in cases where potential fraud is identified), allowing them the ability to disseminate information, propagate new prescribing guidelines and expectations, promote pain management alternatives to opioid therapy, monitor and respond to administrative prescribing information, and prioritize and reimburse effective treatment options. Payers can also prioritize reimbursement for overdose prevention products such as naloxone, use formularies to promote abuse deterrent formulations, and require prior authorization or deny reimbursement for prescriptions or prescription combinations that could result in patient harm.(31)

BACKGROUND OF THE HFPP

The HFPP is a voluntary, public-private partnership between the federal government, state agencies, law enforcement, private health insurance plans, employer organizations, and healthcare anti-fraud associations to identify and reduce fraud, waste, and abuse across the healthcare sector.(5) As of November 2016, HFPP partners included 70 representatives from seven federal agencies, 38 private payer organizations, 14 State Medicaid or healthcare Agencies, and 11 insurance and healthcare anti-fraud associations. HFPP partners regularly collaborate, share information and data, and conduct cross-payer studies to achieve these objectives. Given the HFPP's broad membership, encompassing a variety of players that are interested and involved in the detection of fraud, waste, and abuse in the healthcare system, it is positioned to examine the opioid crisis and develop key recommendations from a unique perspective.

THE OPIOID CRISIS IN THE SPOTLIGHT

This initiative was conducted as a corollary to recent notable efforts to highlight the problems of opioid misuse and OUD in the U.S. and the roles that public and private payers can play in addressing these issues.
These works include:

- **Facing Addiction in America. The U.S Surgeon General's Report on Alcohol, Drugs, and Health**
- **Centers for Medicare & Medicaid Services (CMS) Opioid Misuse Strategy 2016**
- **Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths**
- **Changing Course: The Role of Health Plans in Curbing the Opioid Epidemic by the California Health Care Foundation**

The HFPP seeks to expand upon these works by outlining its approaches regarding opioid misuse and OUD, demonstrating the HFPP's current efforts in this field, and detailing effective practices that payers can implement to address these issues.

HFPP APPROACHES REGARDING PRESCRIPTION OPIOID USE AND MISUSE

Several HFPP partners have taken a particular interest in the further study and consideration of ways in which payers can influence and impact prescription opioid misuse and OUD in the U.S. and dedicated themselves as Partner Champions toward this effort. These HFPP Partner Champions have committed themselves to the creation of an HFPP White Paper that describes the best practices for serious consideration by all healthcare payers and other relevant stakeholders to effectively address and minimize the harms of opioids while ensuring access to medically-necessary therapies and reducing fraud, waste, and abuse (see pg. 3 for the list of HFPP Opioids White Paper Partner Champions).

CREATION OF THE HFPP APPROACHES RELATED TO PRESCRIPTION OPIOID MISUSE AND OUD

The HFPP Approaches related to prescription opioid misuse and OUD were developed to provide the guiding principles for the HFPP's recommended actions. The HFPP Approaches reflect the individual input of the HFPP partners regarding their priorities and experiences in dealing with opioid misuse across their patient populations and coverage areas. Input was provided by multiple partners, modifications were made to address this input, and revisions were made until all participating partners were satisfied that the final language reflected what they believe are the HFPP Approaches related to prescription opioid misuse and OUD.

In October 2016, the HFPP convened a special session of its membership for the purpose of discussing what the HFPP can do in regards to the increasing problems of opioid misuse and OUD. During this session, the Partner Champions articulated the HFPP's approaches with respect to the control of prescription opioid fraud, waste, and abuse and identified feasible strategies representing best practices. Specifically, the Partner Champions identified three core approaches reflecting their mission. The approaches served as guiding principles for the HFPP's recommended actions for addressing prescription opioid misuse and OUD, all of which should be strongly considered by all payers and other relevant stakeholders in the U.S. This framework was developed, in part, on the HHS and CMS priority areas for addressing opioid misuse and OUD (please see Appendix A for more information).(6, 7)

HFPP Approach 1: Share resources, policies, and practices that connect patients to care that is best suited to their needs and achieves optimal outcomes, ultimately reducing opportunities for fraud, waste, and abuse related to opioids.

HFPP Approach 2: Identify and mitigate potentially fraudulent, abusive, or wasteful activities related to opioids.

HFPP Approach 3: Engage in innovative studies and information sharing techniques within the HFPP to identify and share effective opioid misuse and OUD mitigation strategies.

WHITE PAPER ORGANIZATION

The HFPP initiated this White Paper to describe effective and widely accepted payer strategies to reduce inappropriate opioid prescribing as well as reduce the unintended harms of prescription opioids when they are prescribed for medical use. In the sections to follow, we describe a set of effective prescription opioid management strategies that are in concordance with the approaches of the HFPP. Specifically, this White Paper presents academic evidence and implementation examples of payer strategies (where available) related to the following prevention topic areas:

- Provider Education and Communication
- Patient Education and Communication
- Promotion of MAT
- Non-Opioid Pain Management Alternatives
- Data Informatics and Information Sharing
- Prescription Drug Monitoring Program (PDMP) Information
- Drug Utilization Reviews

Each section of the White Paper presents a description of the specific strategy or category of strategy, explaining the way in which the strategy is intended to impact the problem of prescription opioid misuse. Following this description, individual aspects of the strategy are presented along with academic evidence regarding its use and effectiveness in past settings. Finally, each section presents specific examples where available about the strategy as implemented by HFPP partners.

Please see Appendix A for an explanation of the methodology.

HFPP APPROACH 1: SHARE RESOURCES, POLICIES, AND PRACTICES THAT CONNECT PATIENTS TO CARE THAT IS BEST SUITED TO THEIR NEEDS AND ACHIEVES OPTIMAL OUTCOMES, ULTIMATELY REDUCING OPPORTUNITIES FOR FRAUD, WASTE, AND ABUSE RELATED TO OPIOIDS

Patient health and well-being are central to the HFPP's mission. In this vein, the HFPP supports sharing best practices that encourage appropriate care and prescribing practices, reduce barriers to resources that protect patients receiving medical-necessary opioid therapy from the harms of opioids, and minimize the potential for fraud, waste, and abuse in the healthcare system.

HFPP PRIORITY ACTIONS FOR APPROACH 1

- Train providers on the CDC Guideline for Prescribing Opioids for Chronic Pain.(1)
- Promote access to and usage of MAT.
- Promote the availability of naloxone.

This section provides an overview of strategies in support of Approach 1, reviews the evidence base behind each strategy, and discusses specific examples of implementing each strategy as provided by HFPP partners.

PROVIDER EDUCATION AND COMMUNICATION

Distribution of Clinical Guidelines on Opioid Prescribing

EXAMPLE OF CONNECTING PROVIDERS TO RESOURCES

Anthem conducts provider outreach through various websites with information on prescription drug misuse and diversion and CMS' Medicare Learning Network (MLN) Matters publications and provider newsletters. Among other things, these forms of outreach encourage the use of safe alternatives to opioids, non-opioid analgesics, and non-pharmacologic treatments.

Clinical guidelines on opioid prescribing have recently been shown to both improve physician knowledge on prescribing recommendations and influence prescribing rates in the acute care setting.(32, 33) Over the past decade, several states, including Washington, New York, Arizona, Utah, California, and Ohio, have issued guidelines on opioid prescribing in an attempt to address the opioid misuse crises in their states. Most recently, the CDC published its Guideline for Prescribing Opioids for Chronic Pain, which provide recommendations on 1) initiation or continuation of opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) the assessment of risk and addressing harms of opioid use.(1) The introduction of these guidelines offers national practice standards to which providers can refer, rely, and be expected to follow when treating pain (note that the guideline does not apply to palliative care). For example, the CDC recommends that before starting and periodically during opioid therapy, clinicians should discuss with patients the known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy. The guidelines also recommend that when opioids are started, clinicians should prescribe the lowest effective dosage.

Research suggests that adherence to clinical guidelines is higher when the information is disseminated to providers.(34) A high-profile campaign aimed at changing provider behavior on opioid prescribing habits was launched in August 2016 by the U.S. Surgeon General. The Turn the Tide Rx Campaign encourages improved prescribing practices and acknowledges the role of clinicians in addressing the opioid crisis by asking them to take a pledge and commit to fighting the opioid problem in the U.S. Specifically, the Turn the Tide Rx Campaign calls on providers to: 1) educate themselves about how to treat pain safely, 2) screen patients for OUD and refer for or provide evidence-based treatment, and 3) talk about and treating OUD as a chronic disorder to change social norms. The campaign website allows clinicians to "join" the campaign and aggregates many existing publications and resources from the CDC including their new guideline and fact sheets on PDMPs and a Total Daily Dose and morphine milligram equivalents Conversion Calculator. Also available are materials from the Substance Abuse and Mental Health Services Administration (SAMHSA), including a MAT pocket guide and overdose toolkit, and the National Institute on Drug Abuse (NIDA), with links to validated screening tools.

While data on reach, provider behavior change, and patient outcomes associated with the campaign will not be available for some time, research suggests that these types of resources are effective in increasing the use of and adherence to clinical guidelines.(35)

The distribution of clinical guidelines to providers is a strategy can easily be adopted by payers, such as by sending materials promoting the new CDC guideline by mail, electronically, or other effective media. The next two sections describe additional ways that payers can ensure that the most up-to-date information is distributed to providers through Continuing Medical Education (CME) and education outreach visits (also known as public health detailing campaigns).

Continuing Medical Education

Efforts to educate providers through CME may be an effective way to address the opioid crisis by improving provider knowledge and practices. One option payers can take to increase the use of CME is to actively encourage all network providers, with enhanced outreach to those with high prescription rates, to take an approved course on opioid prescribing guidelines. Payers may consider developing a list of recommended courses from which providers can select a course on the CDC or equivalent prescribing guidelines. Current opportunities for CME on this topic are available through a variety of sources, including schools of medicine, medical societies, and federal agencies.

PROVIDER EDUCATION IN CALIFORNIA

The California Department of Health Care Services administers the state's Medicaid program. To combat prescription drug misuse, the agency promotes a series of educational videos for providers and consumers. These include "The Power of the Pen," a one-hour, self-paced learning module with CME credit about key issues in referring and prescribing. This training also increases provider awareness of the mistakes in prescribing practices that can contribute to prescription drug misuse. The Medical Board of California, a partner organization, also hosts training on guidelines for prescribing controlled substances and offers CME credit about pain management.

CME offerings have been shown to improve knowledge and change prescribing behavior. For example, in 2013, Boston University School of Medicine launched a new CME course developed through funding from manufacturers of extended-release/long-acting (ER/LA) opioid analgesics called Safe and Competent Opioid Prescribing Education (SCOPE of Pain).(36) As a result of this CME offering, provider knowledge increased significantly and 87 percent of providers intended to change prescribing practices immediately after the course. When asked the same questions two months later, provider knowledge was still higher than it was before course and 86 percent reported implementing practice changes.

While not specifically focused on opioids, a 2009 systematic review of the literature on CME's effect on provider behavior (focusing on meetings and workshops, not virtual presentations) examined 81 studies from 1999 to 2006, including 11 that targeted preventive care, 13 about prescribing, three on test orders, 41 covering general management of care/conditions, and six focused on other behaviors.(37) The review found that CME meetings are more likely to change professional practice for less complex behaviors (like prescribing) than more complex behaviors (such as general management of a condition). It also found that providers were unlikely to change their behavior if the perceived consequences of the behavior were not serious for the patient (for example ordering tests). It also suggests that mixed interactive and didactic education was most effective. Interactive education alone appeared to be least effective. This evidence is useful in demonstrating that CME targeting opioid prescribing behavior that utilizes a mixed interactive and didactic format may be a useful strategy to educate providers and achieve intended prescribing behaviors.

CENTENE CORPORATION'S PHARMACY BUZZ

Centene Corporation's provider education efforts include an informative webinar called Pharmacy Buzz for both prescribers and pharmacists about concurrent use of opioids and benzodiazepines. The company also distributes mailings and newsletters to instruct providers on how to enroll in the Controlled Substances Prescription Monitoring Program (PMP). Data mining and data analytics drive provider accountability efforts, as Centene reviews the PDMP and e-prescribing, and then flags for review the outlying prescribers, pharmacies, and members who are dispensing or using high volumes of opioids.

Education Outreach Visits

Modeled after pharmaceutical sales strategies, outreach visits are in-person meetings with providers to educate them on new guidelines, clinical practices, or approaches to care. Outreach visits may include detailing campaigns (one-to-one educational visits), audit and feedback strategies, delivery of printed materials, or some combination of these strategies. Payers can use this approach to balance pharmaceutical representative office visits and help to increase knowledge, improve adherence to the new CDC guideline, and ultimately change opioid prescribing behavior.

The evidence for this strategy is promising. While not specifically focused on opioids, a 2012 Cochrane review of 69 studies (and more than 15,000 health professionals) examining the effect of educational outreach visits found that education outreach visits may be effective in changing provider prescribing behavior. A related review of 140 interventions employing audit and feedback (38)— a strategy to improve professional practice through the use of performance feedback that benchmarks a provider's clinical practice to a target outcome— found that, much like other types of outreach visits, audit and feedback "generally leads to small but potentially important improvements in professional practice" and "may depend on baseline performance and how the feedback is provided."

More recent evaluations of public health detailing campaigns—largely modeled on pharmaceutical sales strategies, but oriented around public health priorities—to change provider behavior around opioid prescribing offer similarly positive results with varying strength of evidence. On the low evidence end, a 2011 evaluation of a rural North Carolina detailing campaign on chronic pain suggested that the intervention changed prescribing practices (although the design was weak and did not report prescription data or self-reported provider prescribing patterns).(39) A 2011 evaluation of a Utah detailing campaign specifically designed to change opioid prescribing patterns offers stronger evidence and found that visits were associated with improved self-reported opioid prescribing practices.(40) The strongest evidence of effectiveness of this type of campaign (41) evaluated provider knowledge and behavior change after a New York Department of Health and Mental Hygiene campaign to increase adherence to the 2011 New York City judicious opioid prescribing guidelines among Staten Island healthcare providers.(42)

Examples of HFPP Efforts to Educate and Communicate with Providers

Provider education is a considerable area of focus for the HFPP and many partners are currently using or have plans to implement education efforts. Some specific examples reported by the partners include:

- Offering CME videos to educate providers on prescribing.
- Requiring a CME course for all prescribers with Drug Enforcement Administration registration status.
- Providing anti-fraud education at numerous Pharmacy Diversion Awareness Conferences held across the U.S., which are designed to assist pharmacy personnel with identifying and preventing diversion activity and have thus far been presented in 36 states.
- Using or planning to use one-on-one consultations and coaching to educate providers about appropriate prescribing practices, proper use, and safe storage and disposal.

Partners also identified potential barriers for provider education and adherence to prescribing guidelines, including the following:

- Providers often feel that state agencies are overstepping their authority by questioning provider prescribing practices.
- “Prescriber Prevails” provisions in certain states allow prescribers to overrule any prescribing guidelines or formularies they choose if they find their original selection to be medically necessary and warranted. For example, if a brand name drug is not contained in a payer formulary and education efforts are made to change providers prescribing practices (e.g., from OxyContin to a generic or a pain reliever with a lower potential for misuse), the provider can still make the determination to continue with the OxyContin as a treatment and the payer must cover the cost.

PATIENT EDUCATION AND COMMUNICATION

Patient education and communication seeks to change knowledge, attitudes, behavioral intentions, and ultimately, patient behavior. Payers most effectively reach consumers by correctly matching audience segments with the most salient messages and tools and by utilizing a number of approaches to reach them.

USE OF EDUCATION AND CASE MANAGEMENT TO REACH PATIENTS AT RISK

When Highmark Blue Shield flags patients as potentially having a problem with opioid misuse, they are brought into a multi-step approach that includes education and case management services. These steps will attempt to engage the patient and connect them with in-house or external rehabilitation opportunities.

Audience Segmentation

For payers that aim to target all insured patients, a large and heterogeneous group, designing education materials and health communication tools requires audience segmentation. Segmentation is considered a fundamental mechanism of "consumer-based," or "consumer-oriented" health communication and allows marketing and communication experts to make informed decisions about which audience(s) to target and how to do so.(43, 44)

With respect to educating patients about opioid misuse and OUD, payers may consider using available claims data to create patient profiles, segment target audiences, and conduct data-driven outreach. Profiles can be developed or enhanced by collecting information about patients through a voluntary targeted survey on intentions and behaviors. Segments may be developed based on risk-status (e.g., people at-risk for use and/or misuse and those who are not), role (e.g., patient/caregiver), age, sex, health status, or any combination of these or other factors.

Payers may look to examples from approaches to usher in antibiotic stewardship, defined as "the optimal selection, dosage, and duration of antimicrobial treatment that results in the best clinical outcome for the treatment or prevention of infection, with minimal toxicity to the patient and minimal impact on subsequent resistance."(45) While the problems and consequences of poor antibiotic stewardship are much different than those relating to the prescribing of opioids, given the shared goals of reducing the use and misuse of opioids and antibiotics, payers may consider using the lessons learned from the antibiotic stewardship efforts to better target communication to patients about appropriate opioid use.(46)

In their study, Smith et al. (2015) identified profiles of U.S. adults based on shared stewardship intentions and found that a "nontrivial number of participants intended to engage in problematic antibiotic-related behaviors and did not intend to engage in recommended prevention behaviors." Using latent class analysis, the authors

identified three groups—stewards (those who plan to follow the guidelines), stockers (those who reported holding on to antibiotics for future use), and demanders (those who reported past behavior and future intention of asking providers for antibiotics) that require different messaging to reach the intended goals: to encourage stewards to follow through on their intentions, to encourage stockers to dispose of their antibiotics, and to influence demanders to accept medical advice when an antibiotic is not indicated and to dispose of their leftover antibiotics.

Segmenting patients by intentions/behaviors with regards to opioid prescriptions could help payers better target messages and disseminate tailored communications that are most salient to the recipient. For example, stewards may be those who are more likely to adhere to the CDC guideline and seek non-pharmacologic or non-opioid pharmacologic therapies for chronic pain and stockers may be those who are likely to ask for an opioid prescription/have received an opioid prescription for chronic pain in the past.

Patient Education Resources

Using existing materials or creating new education tools, payers can utilize any number of approaches to getting information to patients. Some potential approaches include:

- Direct to patient outreach
- Mass media and advertising approaches
- Provider-patient education

Appendix B contains more information about these approaches and about existing education tools.

Examples of HFPP Efforts to Educate and Communicate with Patients

HFPP partners noted several approaches for educating and communicating with patients. Examples of these approaches include:

- Providing nurse case management programs and integrated care teams to help manage patient prescription usage and provide appropriate education.
- Relying on mass media. One partner in particular has conducted significant media outreach to inform the public about prescription drug fraud. In addition to their media efforts, this partner has also reached out to the public directly with videos.
- Working with other organizations, such as the state department of health or a behavioral health vendor, to provide or create patient education programs.

PROMOTION OF MEDICATION-ASSISTED TREATMENT (MAT)

MAT combines one of three Food and Drug Administration (FDA) approved medications (methadone, buprenorphine, and naltrexone) with behavioral therapy for preventing relapse and for maintenance treatment of OUD.

Research demonstrates that MAT is a cost-effective method that is more effective at retaining patients in treatment and reducing opioid misuse than approaches such as tapering, detoxification, or abstinence, which are all associated with higher rates of relapse.(47-50) MAT is also associated with reductions in substance use, mortality, treatment dropouts, and Human Immunodeficiency Virus (HIV) and Hepatitis C infections, as well as improved psychosocial functioning and overall quality of life.(51-53) Payers can support MAT through assuring coverage for MAT-related services and working to maintain an adequate number of MAT providers within their network.

The three primary medications used for MAT are:

- **Methadone** is a long-acting opioid agonist that, when used for treatment of opioid addiction, may be dispensed only by federally regulated opioid treatment programs. It is used during the detoxification and maintenance phases of treatment.(54) Methadone is commonly used to assist with detoxification or to provide opioid replacement therapy for patients who are dependent on opioids.
- **Buprenorphine** is a partial opioid agonist that is also used during the detoxification and maintenance phases. Naloxone, an opioid antagonist, can be added to buprenorphine products to increase the likelihood of opioid abstinence during treatment and decrease the likelihood of diversion and misuse.(55-57) Further, because buprenorphine is a partial-agonist, it is associated with a lower risk of respiratory depression and accidental overdose than full agonists.(58) While buprenorphine can be prescribed in opioid treatment programs, the majority of physicians prescribe it in office-based settings.(59) Physicians are required to complete a training course in order to be authorized to prescribe buprenorphine and in November 2016, HHS announced that it would allow nurse practitioners and physician's assistants to apply for a waiver to prescribe buprenorphine.(60) An implantable form of buprenorphine was approved by the FDA in May 2016.
- **Naltrexone** is an opioid antagonist offered in both short- (oral) and long-acting (injectable) forms.(58) It can only be used during the maintenance phase of treatment, as individuals must be completely detoxified prior to starting naltrexone or they will experience immediate opioid withdrawal.(54) Naltrexone blocks opioid receptors, thus it inhibits the effects of opioids when a patient is on the medication.(58) Unlike methadone and buprenorphine, naltrexone is not a controlled substance.(58)

Despite the evidence in support of MAT's effectiveness, the use of MAT has been limited. An analysis of Medicaid data on over 14,000 OUD treatment episodes between 2007 and 2009 found that 63 percent of patients did not receive MAT.(61) A 2011 study found that 45 percent of addiction treatment programs for substance use disorders did not provide MAT and another 2011 study found that, even in programs that provided MAT, 65 percent of patients did not receive MAT.(62, 63)

More recently, in 2014, SAMHSA estimated that of the 2.4 million individuals with an OUD, nearly 80 percent (1.9 million people) do not receive treatment.(64, 65) The lack of treatment presents a unique opportunity for payers to link patients with signs of an OUD to MAT (and other treatments, such as counseling, as appropriate).

Strategies to Overcome Barriers to MAT Access and Use

A number of barriers limit patient access to MAT. Many prospective patients and their families are either unaware of MAT or its effectiveness. Abstinence-only treatment models persist, and there is limited attention to MAT among many abstinence-only advocates and organizations. In many areas there is an insufficient quantity of behavioral health and treatment services, as well as physicians with MAT experience. This problem is particularly severe in rural areas.(63, 66-68) Recent efforts have been made to address this access issue. For example, the President recently signed legislation investing $1 billion over two years to expand access to treatment; SAMHSA recently increased the number of patients that a physician can treat with buprenorphine to 275; and the Controlled Substances Act was amended by the Comprehensive Addiction and Recovery Act of 2016 (CARA) to allow physician assistants and nurse practitioners to apply for waivers to prescribe buprenorphine at the 30 patient level, increasing to the 100 patient level after one year.

Even when available, the use of MAT may present challenges. Payers may place limits on MAT dosages prescribed or other medication limits, require prior authorization to initiate treatment, and provide insufficient coverage for concurrent counseling and step therapy.(69, 70) Fear of diversion and low patient utilization may also lead many providers to avoid prescribing MAT or prescribe it at insufficient dosages.(63)

Eliminating barriers to MAT can help ensure access for patients who are vulnerable to relapse.(71) Fortunately, there are several evidence-based strategies that are effective in promoting MAT and overcoming barriers to access and use. Examples of strategies that may be effective in increasing MAT adoption include:

- **Provider education.** Training and increased experience using MAT have been shown to change provider attitudes regarding MAT and reduce false impressions. Clinicians with greater experience treating patients with buprenorphine/naloxone combination therapy were more likely to believe treatment access barriers

New information technologies. The use of innovative information technology can lead to increased knowledge of MAT and ease access to MAT services. An example of this is SAMHSA's mobile application, MATx, which provides information on the benefits of MAT, clinical support tools, and locations of the closest qualified treatment center.(73) This application also provides information on training necessary to become a MAT provider.(73)

- **New pharmacological formulations.** IAnother promising development to facilitate MAT is the approval of a new implantable form of buprenorphine, which was approved by the FDA in May 2016. This form of buprenorphine provides a continuous, low dose of buprenorphine for six months and can be used in patients who are using low or moderate doses of other forms of buprenorphine.(74-76) It is thought that implantable buprenorphine will increase adherence, as patients cannot forget to take or refill prescriptions.
- **Screening, brief intervention, and referral to treatment (SBIRT).** SBIRT is an evidence-based approach that is used to identify and prevent unhealthy alcohol use or alcohol or drug use disorders.(77, 78) Traditionally, SBIRT is brief (e.g., 5-10 minutes for brief interventions; 5-12 sessions for brief treatments).(77) Specific behaviors related to unhealthy alcohol and drug use are targeted.(77) While SBIRT is often thought of related to unhealthy alcohol use, the approach is also used for unhealthy drug use.(78, 79) The SBIRT approach has been adapted specifically for use with patients with OUD. The Brief Negotiation Interview (BNI) and Emergency Department (ED)-Initiated Buprenorphine/naloxone for Moderate/Severe OUD is an SBIRT approach that is combined with ED-initiated buprenorphine treatment in order to expand access to MAT.(80-82) BNI with follow up is a promising approach to increase access to treatment for patients with OUD.(82)
- **Telehealth.** Telehealth uses technology to aid in the delivery of virtual medical and health services. Telehealth is used to train physicians to become MAT providers, expands the reach of the addiction professional workforce and the existing pool of MAT providers, and supports remote forms of behavioral therapy to make existing trained professionals more accessible to those in underserved or isolated communities.(83)

Expansion of MAT and further research on which of the drug and therapy combinations are most effective for different individuals and during different phases of treatment is warranted. Research demonstrates the effectiveness of MAT options but the level to which this effectiveness fluctuates by patient type is less clear. Patients vary widely in their levels, severity, and duration of use, life experiences, community support, and motivation to recover, and it is unclear which patients are most likely to benefit from each of the three MAT treatments.(84) An evaluation comparing the utilization and effectiveness of MAT options (methadone, buprenorphine, and naltrexone) would provide essential evidence in support of more effective MAT implementation across different clinical practice settings and patient types, and support improved recovery outcomes across the U.S. Identifying optimal MAT models of care in order to better understand how to better facilitate effective treatment would be valuable information to payers.(85)

Examples of HFPP Efforts to Expand MAT

The HFPP supports expanded screening, diagnosis, and treatment of OUDs, including increasing access to MAT. Examples of actions reported by the partners include:

- Providing access to OUD treatment interventions such as covering MAT.
- Working with a behavioral health vendor to provide behavioral interventions.
- Adding buprenorphine to California's state Medicaid formulary without restrictions in June 2015.(86)
- Covering inpatient and outpatient substance use disorder treatment and providing a high-touch care management program (intensive higher utilization management programs lasting 52 weeks) with care coordination for patients with severe substance use disorder needs.
- Removing prior authorization requirements on buprenorphine and naloxone combination product sublingual films and naltrexone injections in late 2015 and restrictions on detoxification to aid patients in receiving treatment somewhere.
- Monitoring aberrant patterns of MAT use to detect fraud, waste, and abuse.

PROMOTION OF NALOXONE

Naloxone is an FDA-approved opioid antagonist that can immediately reverse the effects of an opioid overdose by reversing and preventing binding of opioids with receptors in the brain. At a biological level, opioids act on four types of receptors located on the cell membrane of neurons (mu, kappa, delta and ORL1). Overdose from opioids occurs when opioids bind to mu opioid receptors in the brain stem, reducing the body's sensitivity to carbon dioxide, which in turn decreases respiration.(87)

Naloxone displaces the opioid at the receptors, reversing the respiratory depression caused by the opioid overdose and effectively reversing potentially fatal opioid effects within a few minutes.(88) In fact, naloxone, a non-scheduled prescription drug, has no potential for misuse or overdose, nor does it have any pharmacological activity in the absence of opioids or other opioid antagonists.(88-90) Among individuals under the influence of opioids, naloxone may cause withdrawal symptoms such as nervousness, restlessness or irritability, body aches, fever, chills, diarrhea, dizziness, and weakness.(91)

Naloxone can be administered by a layperson, given repeatedly without fear of causing death, and is not subject to misuse. The drug is simple and safe enough that even family members and friends may administer it in an emergency situation.(91) Naloxone is available as an injectable product and in an auto-injector form. In addition, naloxone is manufactured in an intranasally-administered form developed to eliminate the risks and difficulties of injection by delivering a precise, consistent dose of medications.(92, 93) Approved intranasal naloxone is as effective as intravenous injection.(94-96) Some states also allow standing orders for naloxone or have established collaborative practice agreements for the purpose of increasing access to naloxone.

Naloxone Risks

Persons given naloxone are at risk of recurrence of respiratory depression if their naloxone dose wears off while there are still opioids in their system. This can be easily addressed by giving a second dose of naloxone (though it is also important to quickly connect that person to emergency medical treatment).(97) However, a second dose is not always necessary, and a single-dose administration of naloxone has been demonstrated to be effective in formal medical settings.(89) Adverse reactions to naloxone are rare. A Norwegian study of paramedic-administered naloxone found that 0.25 percent experienced adverse reactions severe enough to require hospitalizations, while roughly 45 percent of all cases reported some of the non-life threatening acute withdrawal symptoms.(98)

While there may be concern that liberal access to naloxone results in moral hazard in the form of excess opioid misuse in the face of fewer consequences,(99, 100) studies have shown that heroin users consistently report that they are not more comfortable using heroin frequently or in higher doses because of naloxone availability.(89, 101, 102) Providers may have concern as to whether co-prescribing naloxone for patients with pain increases provider liability. In fact, researchers have reported that prescribing naloxone is not associated with legal risks any greater than prescribing for any other medication.(103) Via state Good Samaritan laws, clinicians in some states are also given explicit legal protection prescribing naloxone, and in some instance this protection is extended to prescriptions issued to friends and family members.(103)

THE DEPARTMENT OF VETERANS AFFAIRS (VA) OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION (OEND) PROGRAM

The VA OEND program is a risk mitigation initiative that aims to decrease opioid-related overdose deaths among VA patients. The issuance of naloxone constitutes just one component of the OEND program; providing education regarding opioid overdose prevention, recognition of opioid overdose and rescue response comprise other key components. OEND is used by the VA in conjunction with engaging in a risk-benefit discussion and obtaining informed consent for chronic opioid therapy; urine drug screening for illicit drug use and prescription adherence monitoring; minimizing co-prescription of sedatives; substance use disorder (SUD) specialty treatment; opioid agonist treatments, such as buprenorphine and methadone; mental health treatment; and suicide prevention and safety planning. VA has published on-demand OEND education and training that may be accessed by the public, which includes: "Introduction to Naloxone for People Taking Prescribed Opioids," "How to Use the VA Auto-Injector Naloxone Kit," and "How to Use the VA Naloxone Nasal Spray."

Effective Strategies to Promote Naloxone Distribution and Use

Research demonstrates the effectiveness of naloxone for preventing opioid overdose deaths.(104-107) A 2013 study found that naloxone distribution to heroin users is cost-effective.(108) Recent research focuses on increasing knowledge about naloxone and how to increase its effectiveness by using training and opioid overdose education programs.(109-112) The train-the-trainer model is cited as an effective and efficient way to increase both overdose prevention education and the distribution of naloxone.(113) Educational messaging about naloxone with a sympathetic frame has been shown to increase public support for its distribution. (114) Even with increased support for prescribing and use of naloxone, studies suggest that translating this support into practice to enhance uptake of naloxone prescribing is challenging.(100, 115-117) Factors cited as being influential in altering practice are changing medical community norms through professional organization endorsement, leadership and institutional support for naloxone, and dissemination of educational materials about naloxone to providers.(100, 115-117)

Examples of HFPP Efforts to Promote Naloxone Distribution and Use

The HFPP supports reducing unnecessary barriers to the availability of, and reimbursement for, naloxone. The HFPP also supports public and community efforts that result in naloxone accessibility in a variety of settings and the provision of opioid overdose education. HFPP partners have undertaken various strategies to increase access to naloxone, including:

- Distributing naloxone to local law enforcement, to aid first responders in treating individuals who overdose. (118)
- Distributing naloxone to patients concurrently prescribed benzodiazepines and opioids or patients with history of overdose.
- Conducting education programs for family and friends to increase awareness of naloxone and how to administer it.
- Eliminating prior authorization requirements for naloxone.
- Partnering with community resources to send patients for training on appropriate use of naloxone.
- Working with first responders to assure there are adequate training resources.
- Covering naloxone when the CDC recommended daily dose (>90 morphine milligram equivalents) for opioids is exceeded, and denying the opioid claim unless a claim for naloxone is on file for the patient.(82)

NON-OPIOID PAIN MANAGEMENT ALTERNATIVES

The struggle to achieve adequate treatment for chronic pain and prevent opioid misuse and OUD has increased emphasis on utilizing non-opioid and non-pharmacologic pain relief alternatives. According to the CDC guideline, non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.

In addition to opioid pain relievers, there are also non-opioid pain medications that can be used to treat pain. Common non-opioid pain relievers include acetaminophen (e.g., Tylenol®), and non-steroidal anti-inflammatory drugs (NSAIDS) (e.g., ibuprofen, aspirin, naproxen).(119) Corticosteroids may also be used to treat inflammatory pain. Other medications that are sometimes used to treat neuropathic and musculoskeletal pain include low-dose tricyclic antidepressants or serotonin and noradrenaline reuptake inhibitors.(119) Anticonvulsants, antiepileptics, and topical capsaicin may also be used to treat neuropathic pain.(120, 121) However, a recent review shows that one antiepileptic, gabapentin, is not effective in treating post-operative pain.(122) Approved indications for various non-opioid pharmacological interventions are listed in the CDC Guideline for Prescribing Opioids for Chronic Pain.(1).

Research studies also have reported on the varying levels of effectiveness of different non-pharmacologic treatments for the management of acute and chronic pain resulting from a myriad of conditions.(123) Additional research is needed. Some examples of non-pharmacologic treatments include cognitive behavioral therapy, chiropractic care, exercise, transcutaneous electrical nerve stimulation, and implantable neurostimulators.

Current Information on Non-Pharmacological Pain Management Strategies

- **Cognitive behavioral therapy (CBT)** is a form of psychotherapy that focuses on identifying, understanding, and modifying thoughts and behaviors.(124) Studies demonstrate that CBT can be effective in the management of chronic pain. CBT has been shown to have small effects on reducing pain intensity and disability and moderate effects on reducing catastrophic thinking with respect to pain and boosting mood. (125-129) CBT programs can vary widely in content and format (e.g., web, individual, group).(130) Because there is no standardized CBT treatment or training for therapists administering CBT, making comparisons across studies and understanding the mechanisms by which CBT affects chronic pain are difficult.(130, 131) It is thought that changes in attitudes toward adopting a CBT pain self-management and mindful approach early in treatment may be the mechanisms by which CBT results in later-treatment changes in pain intensity interference at 4 weeks.(132) Economic models indicate that CBT is cost-effective for the management of chronic low back pain for commercial health plan members.(133) Barriers to be addressed in utilizing CBT for chronic pain include insufficient insurance coverage, lack of transportation, shortage of CBT providers, stigma associated with mental healthcare, and lack of knowledge about CBT.(130)

- **Chiropractic care** involves manual adjustment or manipulation of the spine and is provided by a health-care professional who focuses on the diagnosis and treatment of neuromuscular disorders.(134) Studies show that chiropractic care is beneficial for the treatment of pain related to non-specific chest pain(135); whiplash-associated disorders(136); acute, subacute and chronic low back pain(137); neck pain(138); and chronic tension headache.(139) Exercise in conjunction with chiropractic care may improve outcomes and minimize recurrence.(140, 141) Managing spine pain with chiropractic care is thought to be less costly than treatment from other healthcare providers.(142)
- **Transcutaneous electrical nerve stimulation (TENS)** is a therapy that uses low-voltage electrical current for pain relief. Proper TENS technique includes sufficient dosing and intensity of nerve stimulation.(143, 144) One systematic review found TENS was effective as a therapy for chronic low back pain(145), while another study found that younger and older patients with low back pain had comparable responses with TENS (although older patients required a higher amplitude dose).(146) Recent evidence indicates that both high and low frequency TENS provides pain relief when administered at a strong dose, but at intensity that does not cause discomfort.(147) TENS is inexpensive and has few risks, which makes it a reasonable therapy to consider in additional to other pain management treatments.(148)
- **Implantable Neurostimulators** are implantable devices that deliver electronic impulses to the spine that help block pain signals before they reach the brain. Spinal cord stimulation (SCS) and peripheral nerve stimulation are techniques used for pain relief. Patient selection is of utmost importance to quality of life, improving function, and relieving chronic pain.(149) Complications are reported in 30-40 percent of patients treated with SCS. These complications have led to recommendations by the Neuromodulation Appropriateness Consensus Committee of the International Neuromodulation Society to mitigate the risks, improve the

Examples of HFPP Efforts to Promote Non-Opioid Pain Management Alternatives

The HFPP supports improved access to non-opioid pain management alternatives, including mental health and substance use treatment programs. Partners vary in how they support access to these alternatives and programs, but examples of approaches include:

- Offering non-opioid pain management alternatives that are evidence-based.
- Supporting behavioral health and care management.
- Supporting coverage of chiropractic and acupuncture care for the treatment of chronic pain, even though there are gaps in the evidence base for these services, because of the relatively low cost, the high satisfaction of patients and providers, and the preliminary evidence indicating these lower opioid prescribing rates.(71)

HFPP PRIORITY ACTIONS FOR APPROACH 1

From the evidence-based strategies noted above to share resources, policies, and practices that connect patients to care that is best suited to their needs and achieves optimal outcomes, ultimately reducing opportunities for fraud, waste, and abuse related to opioids, the HFPP recommends these priority actions:

1. **Train providers on the CDC Guideline for Prescribing Opioids for Chronic Pain.** The HFPP strongly encourages payers to consider communication and incentive models that will result in providers achieving knowledge of and adherence to the CDC Guideline for Prescribing Opioids for Chronic Pain.(1) This guideline exists to assure the appropriate and safe utilization of prescription opioids; however, they will only achieve this result when providers are aware of their content and implement their recommendations.

2. **Promote access to and usage of MAT.** The HFPP strongly encourages the promotion of MAT services as part of a complete treatment program through reimbursement policy and provider recruitment and education for patients who misuse opioids or have an OUD. MAT in combination with behavioral therapy is more effective in treating OUDs than behavioral therapy alone, and its use should be widely promoted and reimbursed.

3. **Promote the availability of naloxone.** The HFPP supports reducing unnecessary barriers to the availability of, and reimbursement for, naloxone. The HFPP strongly encourages the promotion of naloxone availability for patients at risk for opioid overdose to prevent the unintended and catastrophic consequences of ineffective management or misuse of prescription opioids. Promoting the availability of naloxone represents a responsible and ethical response to a significant public health crisis while also ensuring access to needed therapies to achieve positive patient outcomes.

HFPP APPROACH 2: IDENTIFY AND MITIGATE POTENTIALLY FRAUDULENT, ABUSIVE, OR WASTEFUL ACTIVITIES RELATED TO OPIOIDS

HFPP PRIORITY ACTIONS FOR APPROACH 2

- Encourage the use of data to identify fraudulent, wasteful, or abusive practices associated with opioids in order to target corrective actions.

Approach 2 aligns with an important part of the HFPP's mission: the identification and elimination of fraud, waste, and abuse of the healthcare system. The HFPP is committed to addressing fraud, waste, and abuse associated with opioid misuse and OUD as well as coordinating and cooperating with law enforcement and other relevant governmental or regulatory bodies to these issues.

This section provides an overview of strategies in support of Approach 2, reviews the evidence base behind each strategy, and discusses specific examples of implementing each strategy as provided by HFPP partners.

DATA INFORMATICS AND INFORMATION SHARING

Payers have several systems to monitor for fraud, waste, and abuse. Each system affects a different stage of the patient management cycle and can be used to mitigate the impact of prescription opioid use in different ways. These data systems include, but are not limited to:

1. **Authorization systems**, either manual or automated, that match requests for prescriptions with formularies and medical policies that are defined by the payer. Authorizations are typically invoked after diagnosis and either pre-authorize a treatment regimen or interact with a point of sales system in a pharmacy.

2. **Claims processing systems** that analyze submitted claims for policy, regulation, payer-defined edits and reviews. Claims processing systems can also be used to examine a patient's medical history (e.g., diagnoses) to make medical necessity determinations about services or supplies billed.

3. **Payer data warehouses**, data platforms populated with adjudicated claims, updated periodically, that allow for advanced data analytics monitoring. Data warehouses are used by payers, such as in their Special Investigation Units (SIUs), to search for fraud, waste, and abuse.

Information system analytics can be used to identify fraud, waste, and abuse related to opioids through various mechanisms. Analytics can be performed to identify the characteristics and patterns of providers that are prescribing opioids inappropriately or with criminal intent. Models or algorithms can be developed to deny payment for prescriptions that do not conform to general prescribing practices, are contraindicated when prescribed with other medications that a patient has received (e.g., benzodiazepines), or that place a patient at risk for developing or continuing problems with OUD. This information can also be used to target patient education efforts regarding the dangers of opioid analgesics, alternatives to opioids for pain management, and the availability and coverage of effective treatment for OUD.

A payer's ability to identify problematic actors and schemes, including those involving providers and patients, can be greatly improved through the collaborative interchange of claims and other payer data; particularly, personally identifiable information (PII), consistent with appropriate patient confidentiality and privacy protections. For example, PII can be used to identify problem providers who mask their activity by balancing prescriptions across payers. While the ability to conduct patient and provider analyses in real time across payers is limited, information from these analyses can be transferred back to payers for integration into their processes, such as prior authorization and case management systems.

Despite the collection of a wide variety of data for purposes of detecting and preventing fraud, waste, and abuse, there are several challenges to the sharing of this data between payers. Data collection systems are designed to support the capabilities and functionality desired by the collecting organization. In order for the data within those systems to be shared in a useful way, it must be organized into standardized formats that can be ingested and analyzed by a variety of systems. Organizations may also differ in the construction of unique patient identifiers (identification keys), making combining data from different sources difficult. Computer processing resources to match patients from different data sources in real-time is computationally intensive and requires dedicated resources. Legal restrictions, privacy and liability concerns, and technological differences between systems within and across organizations are also likely to substantially limit data sharing, such as the integration of prior authorization systems with PDMP data, or the feeding of information from a SIU data warehouse directly back to point of service pharmacists.

Examples of Data Sharing within the HFPP

HFPP partners are making investments to improve the capabilities of their individual systems to detect and prevent aberrant activity. Authorization systems currently vary among the partners, ranging from straight-forward eligibility processing to systems that are integrated with case management systems to enable a patient's past history to be used at the authorization stage. Partners' claims systems have been programmed to recognize suspicious claims based on the analytic algorithms routinely run on repository information. However, to maximize the potential for these data systems to help interrupt opioid misuse, there is a need for coordination of information through information sharing between systems and payers.

One of the purposes of the HFPP is to allow for the combination of payer data in a way that allows cross-payer analysis that would not otherwise be possible. The HFPP has access to resources that enable partners to share data on a regular basis, including, as appropriate, PII, empowering them to monitor and evaluate provider and patient activities across payment organization boundaries. The HFPP, through a Trusted Third Party (TTP) (as of the publication of this paper, the TTP is CSRA, Inc.) consolidates and standardizes claims from individual partners' warehouses or claims systems to run cross-payer analytics on shared data and provide information that can be used to improve the accuracy of the predictive analytics run by each health plan.

PRESCRIPTION DRUG MONITORING PROGRAM INFORMATION

The function of a PDMP is to collect and monitor prescribing and dispensing data submitted by pharmacies and dispensing practitioners to support states in their efforts to prevent the misuse of controlled substances. According to the CDC, 49 states, the District of Columbia and Guam have instituted PDMPs. The design, oversight, and use of PDMPs vary substantially by state or territory.(150)

Some law enforcement agencies are able to use PDMPs to help with preventing the fraud, waste, and abuse associated with opioid prescriptions, though there are some legal restrictions related to privacy concerns.(151) For example, law enforcement may query PDMP databases pursuant to active investigations in 19 states and the District of Columbia, (152) while thirty states require a court order, subpoena, search warrant, or grand jury order to query their PDMPs.(153)

PDMPs may be useful as a healthcare tool. Peer-reviewed literature evaluating the effectiveness of PDMP programs on a variety of outcomes is mixed.(154-157) To date, some studies have shown small reductions in opioid utilization or prescribing, while others have not observed this reduction.(158-165) There are also mixed findings evaluating the effects of PDMPs on opioid-related morbidity and mortality.(158, 165-169) Differences in the utilization and implementation of PDMPs across states may help explain these findings on PDMPs and the differences in findings across studies. Utilization of PDMPs may be impeded because they can be time-consuming to check and difficult to use and access.(153, 170) Evidence-based strategies to increase prescriber use of PDMPs is an area of active investigation.(153)

HFPP partners have expressed a desire to access PDMP data to supplement information currently contained in their own data warehouses. For example, such data could be used to identify where opioids are prescribed with no underlying medical record. The PDMP data would also be an additional source for identifying high prescribers and high users.

One issue to address with respect to PDMP use appears to be the restricted access that payers have to state PDMP data. Although some partners indicated that it would be useful to integrate PDMP data into the payer systems, payer access to state PDMP data has been difficult to obtain. As of September 2015, 32 states and the District of Columbia allow access to representatives of Medicare, Medicaid, and state health insurance programs for the purpose of assisting in fraud investigations (168). Payers should encourage providers to be trained to effectively use their state's PDMP, including how to appropriately interpret results.

DRUG UTILIZATION REVIEWS

Drug utilization reviews are organized, ongoing reviews of prescribing, dispensing, and use of medication, the goal of which are to help protect patients. For example, drug utilization reviews can help identify patients prescribed both opioids and benzodiazepines, which together can exacerbate respiratory depression, the primary factor in fatal opioid overdose. While peer-reviewed literature evaluating the effectiveness of drug utilization reviews is limited, available literature does show a significant reduction in unsafe opioid and central nervous system combination therapy after the implementation of a retrospective drug utilization program in a commercial health plan.(171) The HHS OIG recommends broadening drug utilization review programs to include more drugs that are susceptible to fraud, waste, and abuse.(172)

Examples of systems and information used to perform utilization reviews are:

- **Augmentation of electronic claims management systems and expansion of prior authorization criteria to identify potential opioid misuse or OUD.** Electronic claims management systems can be augmented to require prior authorization for patients without end-of-life care that are prescribed large doses of opioids, have multiple provider episodes resulting in high utilization of opioids, or are started on opioid therapy and have a recent claim within a specified period for a benzodiazepine. In addition, the prior authorization criteria may be expanded to contain medical justification, documentation that the patient has been screened for OUD, and the use of pain management contracts between patients and providers.
- **E-prescribing.** Along with the added protection against theft or tampering of providers' prescription pads, electronic prescribing, or e-prescribing, can facilitate information exchange and enable point of service interruptions of sales. Payers' implementation of e-prescribing is limited by state law. Some states have prevented or delayed implementation of mandatory e-prescribing. As of March 2016, electronic prescribing is required in New York State; however, there are exceptions to the law.

Patient Review and Restriction Programs (i.e. Lock-In Programs)

One strategy that has arisen from drug utilization reviews is the effective use of a lock-in approach to ensure that prescriptions are based on an informed view of the patient. Under a lock-in program, a patient chooses a single provider, a single pharmacy, or both. Payers only impose lock-in after less restrictive steps have been attempted that have been ineffective in curbing "doctor shopping" or the use of multiple, over-lapping prescriptions. Medicaid agencies in forty-eight states and the District of Columbia report having lock-in programs.(173) These programs are intended to improve care coordination between providers and decrease diversion costs.(174) The program design of lock-in programs vary across states with respect to how to determine that patients are "locked-in," the length of the program, and the restrictions of the program.(174)

One payer suggested the use of urine drug screening as a tool to address opioid utilization by using random screenings for lock-in patients. (Some payers recommend first conducting qualitative tests to determine if the substance of interest is present, followed by quantitative tests to determine the level of the substance of interest.) Peer-reviewed literature examining the design and effectiveness of lock-in programs revealed two recent studies that highlighted concerns about unintended consequences such as lock-in programs resulting in significant increases in the likelihood and frequency of out-of-pocket controlled substance prescription drug utilization, or placing constraints on patients with a legitimate need for opioids.(175, 176) Consequently, it is of paramount importance that payers share insights about the optimal design and potential unintended consequences of their lock-in programs.

More recently, CARA granted CMS the statutory authority for Medicare Part D plan sponsors to implement drug management programs for "at-risk" beneficiaries for prescription drug misuse. Plan sponsors may be able to lock-in "at-risk" beneficiaries to certain prescribers and pharmacies for controlled substances.(177)

Examples of HFPP Efforts to Conduct Drug Utilization Reviews

The HFPP partners support conducting drug utilization reviews and reported doing so in variety of manners. Examples include:

- Reporting routinely based on the contents of the data warehouses as a chief strategy for investigations.
- Providing periodic updates from the claims system to the partners' SIUs, which are stored in data warehouses for analysis. Depending on the size and sophistication of the staff, the SIUs perform analytics, generate leads for investigation, and monitor activities such as the prescribing patterns and dispensing patterns of their providers. SIUs identify aberrancies such as high prescribers, including pain management providers, and high users of opioids. The data in claims records also allow SIUs to track the movements of those known or suspected of abusing opioids or having an OUD.
- Producing a monthly report that shows how many providers have prescribed at least 30 controlled

DRUG UTILIZATION REVIEWS AND LOCK-IN PROGRAMS IN ACTION

To combat prescription opioid misuse, one partner has implemented an innovative program where they review their own data on providers and compare it to their utilization. Doctors who are performing poorly are put on corrective action plans, which include education about patient behavior and appropriate prescribing. Those who don't comply are referred to investigations. This partner works with these doctors to identify and refer patients to treatment services and sends those with a high number of prescriptions to a utilization review.

The partner is also implementing a "Lock-In" program for their Medicaid beneficiaries, which will soon expand into their Medicare population. This type of program restricts users to certain doctors or pharmacies, preventing patients from shopping for prescriptions from multiple providers without detection.

substances or where more than 30 percent of all the provider's prescriptions are for controlled substances. The report is sent to a corporate department that reviews the trends of the provider to determine whether they are prescribing appropriately. Defining levels of use for morphine-equivalent doses for their members and the referral of cases to the quality team when the limits were exceeded.

- Defining levels of use for morphine-equivalent doses for their members and the referral of cases to the quality team when the limits were exceeded.
- Enhancing authorization systems for patient-level minimum effective dose (MED) limits that leverage the prescription claim response to the pharmacy to inform them why a claim is being rejected due to a specific patient limit.
- Using claim system edits for high utilizers that require medical justification documentation before a claim is paid.
- Using utilization reviews to identify and monitor pain management providers with a high rate of prescriptions.
- Conducting retrospective drug utilization reviews that notify physicians of safety risks identified through the review and provide appropriate recommendations for management by a letter. Patients are selected for the review based on safety risks that are categorized as clinical rules.

HFPP PRIORITY ACTION FOR APPROACH 2

From the evidence-based strategies noted above to identify and mitigate potentially fraudulent, abusive, or wasteful activities, the HFPP recommends this priority action:

Encourage the use of data to identify fraudulent, wasteful, or abusive practices associated with opioids in order to target corrective actions. The HFPP strongly encourages the use of singular and cross-payer data to identify patients at risk of opioid misuse or OUD, to prevent non-medical use of prescription opioids and drug diversion schemes, and to act upon those findings. Data systems can be used to identify at-risk patients and aberrant or suspicious opioid prescribing or use trends. This information can help direct investigative resources and appropriate interventions. Participation in studies using cross-payer data, such as through the HFPP, is recommended as these studies can be particularly helpful in identifying fraudulent or wasteful activities across organizations and initiating actions based upon these findings. This may include,

- Developing and enhancing data systems that can use plan data to identify patients at risk of opioid mis-management or non-medical use and have the ability to deliver that information in real time.
- Using plan data to identify potentially fraudulent or abusive prescribing practices and refer these providers for potential education, administrative sanction, or law enforcement referral as appropriate.
- Encouraging adoption of a stepped approach to dealing with "at-risk" patients such as case management and adoption of lock-in programs for patients, allowing access to non-emergency care and services but only through restricting access to specific pharmacies for medications ordered by specific prescribers.
- Encouraging the identification and development of best practices for drug utilization reviews across payers.

HFPP APPROACH 3: ENGAGE IN INNOVATIVE STUDIES AND INFORMATION SHARING TECHNIQUES WITHIN THE HFPP TO IDENTIFY AND SHARE EFFECTIVE OPIOID MISUSE AND OUD MITIGATION STRATEGIES

The HFPP supports the creation and dissemination of new information related to best practices in combatting opioid misuse and OUD. The HFPP data resources are unparalleled in the U.S., as no comparable cross-payer collection of timely healthcare payment data exists elsewhere. At the same time, knowledge gaps continue to exist regarding the most effective strategies to reduce inappropriate opioid prescriptions, promote recovery from OUD, and increase the use of opioid alternative therapies for pain management. Here, the HFPP states its commitment to using its considerable data resources to address these questions.

HFPP PRIORITY ACTION FOR APPROACH 3

- Identify and disseminate effective practices across the healthcare sector.

STUDIES FOR FUTURE CONSIDERATION

Analysis using the HFPP's unique cross-payer data source can substantially improve our understanding of effective strategies to prevent prescription opioid morbidity and mortality and fraud, waste, and abuse related to opioid prescribing, misuse, and diversion. This data offers the opportunity to analyze trends among patients and providers across plans, with appropriate confidentiality and privacy protections, and identify the impact of strategies, even on rare events or outcomes.

Examples of studies that the HFPP may consider undertaking in this area include, but are not limited to:

1. **Evaluation of the benefits and effectiveness of different provider and patient education strategies.** HFPP partners support an increased emphasis on provider and patient education efforts to reduce the harms of prescription opioid use and misuse. For example, educating providers on the CDC's opioid prescribing guideline was a primary objective expressed by HFPP partners in the Special Session on Prescription Opioids.(1) Other suggestions included educational outreach visits, direct mail, and web and email contacts. However, very little is known about the effectiveness of these strategies with regards to changing opioid prescribing behaviors or changing behaviors among patients at risk for opioid misuse and OUD. The HFPP offers a unique and almost unprecedented opportunity to monitor and evaluate the effectiveness of health communications and health education efforts across a diverse group of payers, providers, and patients. Specific provider and patient education evaluations of high interest to the HFPP include:

- Evaluating changes in provider prescribing behavior after attending CME training on CDC opioid prescribing guideline
- Evaluating the effect of direct mail, email, and web efforts
- Identifying effective patient communications

2. **Evaluation of utilization of MAT services and the availability of MAT providers by geographic region and/or payer provider network.** MAT has been shown to be an effective treatment of OUD. However, significant barriers exist to greater MAT utilization. The largest of these barriers is a shortage of MAT providers in certain geographic areas or as participants among a payer's network of preferred providers. The HFPP can develop and implement data monitoring algorithms to identify geographic locations or payer networks with comparative shortages of MAT providers and/or MAT utilization.

3. **Description and characterization of the opioid prescribing environment.** Although the problems of inappropriate prescribing are well known, few studies have attempted to quantify the problem systematically. The CDC's opioid prescribing guideline provide an objective, widely accepted set of standards to use to evaluate opioid prescribing. In a study of the opioid prescribing environment, the HFPP can develop a set of algorithms to identify instances of prescribing that fall outside the guideline and classify these by risk of patient overdose, and risk of OUD. Examples of non-guideline prescriptions include:

    - Prescriptions made above a morphine milligram equivalent (MME) of 90 MME/day without titration
    - Prescriptions of opioids concurrently with benzodiazepines
    - Prescription of opioids with no justifying medical diagnosis

    This study can offer a first-of-its-kind comprehensive picture of the prevalence of opioid prescribing problems. The study could also classify providers who inappropriately prescribe opioids and patients who receive inappropriate prescriptions by demographics, region, provider type, and patient diagnosis (or lack thereof).

4. **Description and characterization of prescription and doctor shopping.** Patients may attempt to fill prescriptions at more than one pharmacy, obtain prescriptions for the same condition from multiple providers, or enroll in multiple payers' plans to facilitate the fraudulent fulfillment of prescriptions. However, published research quantifying this behavior is scarce within plans and is nonexistent across plans. This study would be similar to the study characterizing opioid prescribing that is non-adherent to the CDC prescribing guidelines, but would extend the study to identify specific instances that are highly suggestive of prescription fraud or misuse. In particular, the study would identify instances in which:

- A patient filled the same prescription at more than one pharmacy
- A patient filled the same prescription at one or more pharmacies using different health payers
- A patient received duplicate prescriptions from different providers for the same or a similar condition
- A patient receiving duplicate prescriptions filled them using different health payers

Using these and related criteria, the study would present unique information on prescription and doctor shopping. For the first time, the behavior would be quantified in terms of the number of patients engaging in the behavior, the number of prescriptions filled as a result of the behavior, and the cost across payers of fulfilling fraudulent prescriptions. The study could also be used to estimate the prevalence rate of prescription fraud, as well as the regional, demographic, and diagnostic characteristics of patients who perpetrate fraud.

HFPP PRIORITY ACTION FOR APPROACH 3

In support of the effort to engage in innovative studies and information sharing techniques within the HFPP to identify and share effective opioid misuse mitigation strategies, the HFPP recommends this priority action:

Identify and disseminate effective practices across the healthcare sector. The HFPP strongly encourages collaborative efforts to develop and widely disseminate effective strategies to identify: patients at risk of opioid misuse or OUD, providers whose opioid prescribing patterns fail to comply with quality indicators (such as the CDC Guideline for Prescribing Opioids for Chronic Pain), and methods that are particularly effective at preventing or treating OUD. Whenever possible, these strategies should include ways to measure their effectiveness in achieving the intended goals.

CONCLUSIONS

The crisis of prescription opioid misuse and OUDs poses substantial problems for the payer, governmental agency, employer, and law enforcement partners of the HFPP. The health consequences and costs of opioid use have skyrocketed over the last two decades, a trend that has coincided with the increase in number of opioid prescriptions written and the number of people using them for non-medical purposes.(9, 14-18, 23) Despite the quadrupling in opioid prescriptions between 1999 and 2013, Americans have experienced little change in their reported levels of pain.(178, 179)

Many Americans may require the use of opioid analgesics to treat severe chronic pain that is unresponsive to non-opioid pain management options. Fortunately, specific guidance is available to help providers and patients use opioids in a way that maximizes their benefits and reduces their harms. According to the CDC's opioid prescribing guideline, opioid analgesics should be used only as a secondary option to treat pain after other non-opioid alternatives for pain relief have been unsuccessful (note that the guideline does not apply to palliative care).(1) When opioids are prescribed, they should be initiated at the lowest dose possible with dosage increased slowly if the patient fails to respond.(1) When prescribing opioids, patients should be informed of their risks and subsequently monitored to assure that the benefits of the medication are outweighing their harms.(1)

Prescription opioid analgesics can result in substantial patient harms when not prescribed within appropriate guidelines, including OUDs and fatal and non-fatal overdose. These harms have devastating effects on individuals and families across America, substantially increase health care costs, and have increased the need for criminal justice and social services.

The HFPP strongly supports and promotes collective and coordinated action to combat the crisis of negative health consequences that result from the intended and unintended misuse of prescription opioids. The consequences of inaction on this issue are dire in terms of public health impact and increased medical costs. The problems of opioid mismanagement, over-prescribing, diversion, and non-medical use fall squarely within the HFPP's mission to foster a proactive approach to detecting and preventing healthcare fraud, waste, and abuse through data and information sharing. This document contains guidance on specific strategies and priority actions that are supported by evidence, have the ability to reduce the problems of prescription opioid misuse, can be feasibly implemented, and can be promoted without controversy by all HFPP partners. These priority actions should be strongly considered for implementation.

The HFPP is a voluntary public-private partnership comprised of private payers, anti-fraud associations, state agencies, employer organizations, and federal government partners. Its mission is to advance the detection and prevention of healthcare fraud, waste, and abuse through data sharing, collaboration, and collective strategy. To learn more about joining the Healthcare Fraud Prevention Partnership please contact us at TTP@csra.com or visit our website at hfpp.cms.gov.

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APPENDIX A: METHODOLOGY

DEVELOPMENT OF APPROACHES

In October of 2016, the HFPP began working on a White Paper with the initial focus of describing effective and widely accepted payer strategies to reduce the morbidity and mortality from prescription opioid medical and non-medical use. Draft approaches were developed to reflect the priorities of HFPP partners. They were presented for review, discussion, and modification during an HFPP Special Session on Marketplace Fraud and Opioids held on October 20, 2016. Input on the approaches was provided by multiple partners, modifications were made during the discussion to reflect this input, with the revisions visible to all partners in the room, until a point where all participating partners were satisfied with the final statements.

GENERATION OF STRATEGIES FOR DISCUSSION

In addition to the approaches, the HFPP Special Session was used to discuss strategies that payers could implement to address problems associated with the medical and non-medical use of prescription opioids. Discussions were organized around lists of unique strategies gathered directly from partner presentations given via HFPP webinars in previous weeks and additional strategies reported by partners using a standardized strategy elicitation template that was emailed to each partner organization. Templates included prompts requesting information on strategies related to nine topic areas: (1) formularies, (2) patient and provider education, (3) use of safe opioid alternatives, (4) substance abuse treatment services, (5) access to naloxone, (6) coalition building, (7) improving data sharing and e-prescribing, (8) lock-in programs, and (9) other strategies falling outside these topics.

Partners submitted templates to the TTP (as of the publication of this paper, the TTP is CSRA, Inc.), the entity responsible for conducting studies and facilitating other HFPP activities, describing specific strategies used or attempted by their health plan, specific fraud schemes discovered by their plan, lessons learned, information gaps, and ideas for potential future studies. Strategies reported by the partners were organized in Microsoft Excel® (Redmond, WA) and reviewed, de-identified, and de-duplicated by the TTP to generate unique lists of strategies by topic area.

DETERMINATION OF STRATEGIES FOR REVIEW

The TTP used nominal group technique to assess group sentiment regarding the relative value of the strategies discussed in terms of their importance for additional literature review and inclusion in an HFPP White Paper. Nominal group technique is a qualitative research method used to facilitate group discussion, assure that discussion input is contributed by all participants including those that may be sometimes less vocal, and assess group sentiment regarding discussion questions of importance.(180) Lists of unique strategies related to each

approach and further organized by topic area were presented to participating HFPP partners attending the October 2016 Special Session. Partners were prompted to discuss the relative merits and difficulties of each strategy as well as to suggest additional strategies that did not appear on the initial lists. A trained moderator provided prompts to the session participants regarding the desirability and feasibility of each strategy discussed with special emphasis on eliciting discussion from all participating partner organizations. The moderator also prompted session participants to discuss strategies that appear in published studies but were not submitted in the elicitation templates or volunteered during discussion. At the conclusion of each topic area, participants were given an opportunity to volunteer any additional strategy that had not already been volunteered as well as to suggest topics for additional research.

Following the discussions related to each approach, participants were asked to assess the strategies and privately nominate the three strategies that they felt represented the highest value for further review and discussion in an HFPP White Paper. Value was defined as strategies likely to have the greatest impact on morbidity and mortality related to prescription opioids, were within the authority and aligned with the business model of a typical health payer, and were most likely to be feasibly implemented and least likely to face institutional barriers for implementation. Nominations were assessed by the TTP and used to guide the selection of strategies for the White Paper.

REVIEW OF LITERATURE AND DRAFTING OF SECTIONS

Based on the feedback from the October 20 session, the TTP selected eight strategy areas for literature review and presentation in this White Paper: (1) provider education and communication, (2) patient education and communication, (3) MAT, (4) promotion of the distribution and use of naloxone to prevent catastrophic reaction to opioid overdose, (5) promotion of opioid alternatives for pain relief and management, (6) coordination of information systems, (7) payer use of PDMP information, and (8) utilization review facilitated by e-prescribing practices.

For each strategy area, the TTP used Pubmed to search for published articles. To assure that the literature was conducted in a systematic fashion, the TTP focused each review on descriptions of past implementations and evidence of effectiveness of the strategy in mitigating the harms of prescription opioid medical and non-medical use. The TTP conducted a Pubmed search for relevant articles using key search terms. The TTP reviewed the first 10 pages of results for each set of search results first by title, next by abstract, and then finally the full text review. Additional supplemental searches were conducted using Google and Google Scholar, as necessary. (181, 182) The TTP also reviewed information contained in the partner templates, in the notes from the October 2016 Special Session, and in non-academically published materials supplied by partner organizations, and described examples from partners provided by these materials in each section.

WHITE PAPER REVIEW, INPUT, AND FINALIZATION

HFPP partners were given advance notification of the delivery of the draft White Paper and were requested to allocate staff time to its review. The initial draft was disseminated to all HFPP partners. Those receiving the draft were provided with a comment template organized by draft section and given time to review and provide recommendations for revisions. The TTP compiled comments by section, reviewed them for response, made revisions where possible, and documented either the revision or the reason it could not be incorporated. The revised draft was returned to those HFPP partners who had commented previously, giving them additional time to review. Additional comments resulting were incorporated into the revised document where possible. The revised document was submitted to CMS for clearance and revisions were made to the document during the clearance process.

APPENDIX B: PATIENT EDUCATION RESOURCES

POSSIBLE PATIENT OUTREACH AND EDUCATION APPROACHES

Payers can use any number of approaches to getting information to patients. Some potential approaches are highlighted below.

- Direct to patient outreach.
  - To raise general awareness about the opioid crisis, payers could send out newsletters, leaflets, and other tools by mail or email with information on the Turn the Tide Rx Campaign, signposting recipients to the campaign website, and highlighting some of their infographics to engage consumers.
  - To educate consumers about alternative pain management techniques, payers could send out relevant information through the mail, email, or text to specific patients with a history of or potential for opioid use. Payers could invite this select group to participate in a nurse case-management program that encourages use of alternative, non-pharmacologic therapies for chronic pain management.
  - To increase patients' awareness of their personalized risk and ways to mitigate them, payers could consider developing individualized patient portals to show relevant infographics (some excellent examples are already publicly available on the Turn the Tide RX Campaign website), their own risk profiles based on their claims data, tools for prevention, questions to ask providers, and other personalized alerts.
- Mass media and advertising approaches.
  - Payers could consider ways to partner with existing public education campaigns, such as the Turn the Tide Rx Campaign, to further raise awareness and disseminate their materials and key messages.
  - Beyond supporting existing campaigns, healthcare payers could also explore how to use online advertising to target patients and other consumers at risk for opioid misuse or OUD based on browser search algorithms.
  - More traditional direct-to-consumer advertising on television may also be an avenue to explore.
- Provider-patient education.
  - Payers could disseminate materials created by the CDC, SAMHSA, NIDA, American Medical Association (AMA), and American Hospital Association (AHA) to select in-network providers to give to their patient (e.g. pamphlets and fact sheets), showcase in their offices (e.g. posters), and engage patients in discussion (e.g. pocket guides).
  - Payers could also provide select in-network providers with other materials, such as Consumer Reports (which has had a series of reports on opioids) to be stocked in patient waiting rooms.
  - Payers could provide existing materials to pharmacists for use when conducting patient education.

EXISTING OPIOID PATIENT EDUCATION TOOLS

- Public education materials are currently available from a variety of sources and target different types of audiences. The following list is only a small sample of the existing public information but offers payers a number of readily available resources that could be shared with their patient populations.
- U.S. Surgeon General's *Turn the Tide Rx Campaign* features a patient education section that could be used for a variety audiences. Easy to understand information and infographics about types of opioids, managing pain safely, and safe storage and disposal are all available on this site.(184) In addition, the website also promotes SAMHSA's treatment helpline number.
- The HHS opioids page contains patient-directed information about specific drugs, treatment, and treatment related issues such as convincing family members to access care, managing possible insurance questions, and responding to an overdose situation. The site also acts as a portal directing interested readers to additional resources drawn from across HHS agencies.(185)
- The NIDA website has a variety of online patient education tools including videos and pictures and downloadable booklets and fact sheets.(187) They also have several posters that providers can print and place in their offices to spark education sessions with patients.(188)
- The SAMHSA website has a community overdose toolkit as well as a published book called *Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorder* with a chapter dedicated to patient education.(189, 190)
- The CDC has information for patients on their website related to their newly published guideline.
- The Veterans Health Administration (VHA) offers resources for pain management on their website including several YouTube videos: 1) Introduction to Naloxone for People Taking Prescribed Opioids, 2) How to Use the VA Auto-Injector Naloxone Kit, and 3) How to Use the VA Naloxone Nasal Spray.
- Some professional societies, including the AHA and the AMA, also feature patient education information on their websites.

APPENDIX C: HEALTHCARE FRAUD PREVENTION PARTNERSHIP

Current Partners as of 11/30/2016.

7 Federal Agencies

- Department of Defense, Defense Health Agency
- Department of Health and Human Services (HHS), Associate Deputy Secretary's Office
- Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS)
- Department of Health and Human Services, Office of the Inspector General (HHS OIG)
- Department of Justice (DOJ), Criminal Division
- Department of Justice, Federal Bureau of Investigation (FBI)
- United States Department of Veterans Affairs (DVA)

38 Private Plans

- Aetna
- Amerigroup
- Anthem
- AvMed
- BCBS of Alabama
- BCBS of Kansas
- BCBS of Nebraska
- Blue Shield of California
- CareFirst Blue Cross Blue Shield
- Care Source
- Centene
- Central Health Plan of California
- Cigna
- Fidelis Care NY
- Florida Blue
- Emblem Health
- Health Alliance Plan
- Sentry
- HealthSun
- Health Care Service Corporation (HCSC)
- Highmark
- Horizon BCBS of New Jersey
- Humana
- Independence Blue Cross
- Kaiser Permanente
- Magellan Health
- Medical Mutual of Ohio
- ModaHealth
- Molina Healthcare
- Premera Blue Cross
- SCAN Health Plan
- United HealthCare
- Wellcare
- Geisinger Health Plan

11 Associations

- America's Health Insurance Plans (AHIP)
- American Insurance Association (AIA)
- Blue Cross and Blue Shield Association (BCBSA)
- Coalition Against Insurance Fraud (Coalition)
- Delta Dental Plans Association
- National Association of Insurance Commissioners (NAIC)
- National Association of Medicaid Directors (NAMD)
- National Association of Medicaid Fraud Control Units (NAMFCU)
- National Business Group on Health (NBGH)
- National Healthcare Anti-Fraud Association (NHCAA)
- National Insurance Crime Bureau (NICB)

14 State Organizations

- Arkansas: Office of the Medicaid Inspector General
- Arizona: Medicaid Office of the Inspector General
- Arizona: Healthcare Cost Containment System
- California: Department of Healthcare Services
- Connecticut: Department Of Social Services
- Illinois: Department of Healthcare and Family Services Office of Inspector General
- Iowa: Insurance Fraud Bureau (NAIC's representative of the Information Sharing Committee)
- Maryland: Department of Health and Mental Hygiene
- Massachusetts: Office of the State Auditor
- New York: Office Of Medicaid Inspector General
- Ohio: Attorney General's Office (NAMFCU's representative on the Information Sharing Committee)
- Oregon Health Authority
- Texas: HHS Commission Office of Inspector General
- Vermont: Program Integrity Unit, Dept. of Vermont Health Access
- West Virginia: Bureau for Medical Services

APPENDIX D: GLOSSARY OF ABBREVIATIONS

AHA	American Hospital Association
AMA	American Medical Association
BNI	Brief negotiation interview
CARA	Comprehensive Addiction Recovery Act
CBT	Cognitive Behavioral Therapy
CDC	Centers for Disease Control and Prevention
CME	Continuing Medical Education
CMS	Centers for Medicare and Medicaid Services
DUR	Drug Utilization Review
ED	Emergency Department
ER/LA	Extended Release/Long Acting
FDA	Food and Drug Administration
HFPP	Healthcare Fraud Prevention Partnership
HHS	The U.S. Department of Health and Human Services
HIV	Human Immunodeficiency Virus
MAT	Medication Assisted Treatment
MBSR	Mindfulness-Based Stress Reduction
MED	Morphine Equivalent Dose
MME	Morphine Milligram Equivalent
NIDA	National Institute on Drug Abuse
NSAID	Non-steroidal Anti-inflammatory Drug
OEND	Overdose Education and Naloxone Distribution (a program of the VA)
OIG	Office of Inspector General (U.S. Department of Health and Human Services)
ORL1	Opioid Receptor Like - 1 (a receptor widely expressed in the central nervous system)

OUD	Opioid Use Disorder
PDMP	Prescription Drug Monitoring Program
PII	Personally Identifying Information
PMP	Prescription Monitoring Program
Rx	Prescription (Abbreviation of the Latin ‘recipere’ meaning ‘To Take’)
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIRT	Screening, brief intervention, and referral to treatment
SCOPE	Safe and Competent Opioid Prescribing Education
SCS	Spinal Cord Stimulation
SIU	Special Investigation Unit
SUD	Substance Use Disorder
TENS	Transcutaneous electrical nerve stimulation
TTP	Trusted Third Party
U.S.	United States
VA	Veterans Administration
VHA	Veterans Health Administration

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