CHAPTER 16

Mandated report: Opioids and alternatives in hospital settings—Payments, incentives, and Medicare data

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Chapter summary

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 includes a mandate for the Commission to describe how Medicare pays for both opioid and non-opioid pain management treatments in hospital inpatient and outpatient settings, incentives under the inpatient and outpatient prospective payment systems for prescribing opioids and non-opioids, and how opioid use is monitored through Medicare claims data. The Commission's report is due by March 15, 2019.

Medicare uses bundled payments to pay for pain management drugs and services in both the inpatient and outpatient settings. Bundled payments are applied differently in the two settings. The inpatient prospective payment system (IPPS) assigns stays to categories (Medicare severity–diagnosis related groups) based on patients' conditions and sets payment bundles that reflect the average costs of providing *all* items and services supplied during the stay. The outpatient prospective payment system (OPPS) also groups services into categories (ambulatory payment classifications), but on the basis of clinical and cost similarity, and sets payment bundles to cover the costs of providing *integral* items and services along with the primary service. Additional items and services are paid separately or are not paid under the OPPS.

In this chapter

Some observers have questioned whether Medicare's hospital payment systems create financial incentives for providers to choose opioids over non-opioid alternatives. The IPPS and OPPS payment bundles create a financial incentive for hospitals to be cost conscious in selecting items and services. Medicare's quality measurement and reporting programs, along with providers' clinical expertise and professionalism, are designed to balance this financial incentive. Ideally, these balanced incentives result in high-quality outcomes at the best prices for beneficiaries and other taxpayers. However, if opioids were systematically cheaper than non-opioid alternatives, providers might be more inclined to opt for them, especially if doing so did not affect performance on quality measures. We analyzed publicly available prices for opioid and non-opioid alternatives commonly used in the hospital setting to assess the extent of any difference in prices between the two categories of drugs. We found that both opioids and non-opioids are available at a range of list prices, including expensive and inexpensive options for both. Thus, there is no clear indication that Medicare's IPPS and OPPS discriminate against non-opioids. Indeed, hospitals that select more expensive options for clinical reasons have tools available to them, such as reducing length of stay, to partially or fully offset these costs.

Our study is not intended to be an assessment of the clinical appropriateness of the use of opioids versus non-opioid alternatives. Clinicians' decisions about which analgesic drugs to prescribe are based on a multitude of patient-specific factors. Furthermore, we recognize that there are incentives in addition to financial incentives that may have an even greater influence on clinicians' choice of pain treatments, such as effects on patient experience, length of stay, need for additional nursing services, and—most important—the management of potential risks and clinical efficacy. However, these motivations are not unique to the Medicare IPPS and OPPS, so to comply with the mandate's due date, we focused on the extent to which these payment systems introduce financial incentives.

CMS monitors opioid use through claims and other data in the Part D program. The tools used in the Part D program include the Medicare Part D Overutilization Monitoring System, which ensures that Part D plan sponsors implement the opioid overutilization policy effectively; the quality measures to track trends in opioid overuse across the Medicare Part D program and drive performance improvement among plan sponsors; and the publicly available Medicare Part D opioid prescribing mapping tool.

Medicare does not operate similar tracking programs in Part A or Part B. Given concerns about the opioid crisis, policymakers may wish to direct CMS to track

opioid use in hospital inpatient and outpatient settings. If Medicare were to undertake an opioid monitoring program in Part A and Part B, there are structural differences from Part D that would require adaptation of CMS's current monitoring program. There are at least three options for implementing a Part A and Part B opioid tracking program: (1) require prescription drug event–type reporting, (2) include all pain management drugs in Part A and Part B claims, and (3) link Part D opioid use to hospitals responsible for initiation. ■

Mandate for this report: The SUPPORT for Patients and Communities Act of 2018

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act became law. The SUPPORT Act requires the Medicare Payment Advisory Commission to report on opioid payment, adverse incentives, and data under the Medicare program by March 15, 2019. Specifically, the Act calls for the Commission to provide the following:

- a description of how the Medicare program pays for pain management treatments (both opioid and non-opioid pain management alternatives) in both inpatient and outpatient hospital settings;
- the identification of incentives under the hospital inpatient prospective payment system and incentives under the hospital outpatient prospective payment system for prescribing opioids and incentives under each system for prescribing non-opioid treatments, and recommendations as the Commission deems appropriate for addressing any of such incentives that are adverse incentives; and
- a description of how opioid use is tracked and monitored through Medicare claims data and other mechanisms and the identification of any areas in which further data and methods are needed for improving data and understanding opioid use. ■

Introduction

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 requires the Commission to describe how Medicare pays for both opioid and non-opioid pain management treatments in the inpatient and outpatient hospital settings, any incentives under the inpatient and outpatient prospective payment systems for prescribing opioids and non-opioids, and how opioid use is monitored through Medicare claims data (see text box on the SUPPORT Act). The Commission's report is due March 15, 2019.

To meet the requirement of a mandated report, this chapter reviews how Medicare pays for opioids and non-opioid alternatives in inpatient and outpatient hospital settings. In addition, we present data on the extent to which the inpatient and outpatient prospective payment systems introduce financial incentives for prescribing opioids versus non-opioid alternatives and discuss options for addressing any adverse incentives. We also describe how Medicare monitors opioid use through claims and other data in Part D. Finally, we discuss policy options for monitoring opioid use in Part A and Part B.

How Medicare pays for opioids and non-opioid alternatives in hospital settings

Medicare uses bundled payments to pay for pain management drugs and services in both the inpatient and outpatient settings. Bundled payments are applied differently in the two settings. The inpatient prospective payment system (IPPS) assigns stays to categories on the basis of patients' conditions and sets payment bundles that reflect the average costs of providing *all* items and services supplied during the stay. In contrast, the outpatient prospective payment system (OPPS) groups services into categories on the basis of clinical and cost similarity and sets payment bundles to cover the costs of providing *integral* items and services along with the primary service. Additional items and services are paid separately or are not paid under the OPPS.

Inpatient hospital payment for opioids and non-opioid alternatives

Medicare Part A pays for drugs and other pain management services administered during an inpatient hospital stay through the IPPS. The IPPS sets payment

New medical services and technology payments

The inpatient prospective payment system includes a design feature to accommodate hospitals' adoption of innovative, expensive pain treatments. If a new pain drug or other pain management service is too costly to be assigned to an existing Medicare severity–diagnosis related group (MS–DRG), there is a mechanism for a special (additional) payment. Hospitals using certain cost-increasing medical services and technologies can apply for and receive add-on payments for new technologies. CMS evaluates applications by technology firms and others for add-on payments based on criteria of newness, substantial clinical improvement, and the costliness of the service or technology beyond the level of the current MS–DRG payment amount. New-technology payments are additional to the MS–DRG payment and thus are not budget neutral.

To date, there have been no opioid or non-opioid drugs included on the inpatient new-technology add-on payment list. ■

rates to reflect the average costs that hospitals incur in furnishing care.[1] These costs include the provision of all items and services supplied by the hospital during the stay, including pain management.[2]

To account for the patient's needs, Medicare assigns discharges to Medicare severity–diagnosis related groups (MS–DRGs), which group patients with similar clinical conditions that are expected to require similar amounts of hospital resources. Each MS–DRG has a relative weight that reflects the expected relative costliness of inpatient treatment for patients in that group. Providers then have flexibility in determining the mix of items and services to provide for each stay.

CMS annually reviews the MS–DRG definitions to ensure that each group continues to include cases with clinically similar conditions requiring comparable amounts of inpatient resources. When the review shows that subsets of clinically similar cases within an MS–DRG consume significantly different amounts of resources, CMS can reassign them to different MS–DRGs with comparable resource use or create a new MS–DRG. There are special payments for services with insufficient data for CMS to assign them to an MS–DRG (see text box on new medical services and technology payments).

Outpatient hospital payment for opioids and non-opioid alternatives

Any covered nondrug pain management services employed during an outpatient visit are paid under Part B through the OPPS. The OPPS sets payments for individual services (identified by Healthcare Common Procedure Coding System (known as HCPCS) codes) using a set of relative weights, a conversion factor (which translates the relative weights into dollar payment rates), and adjustments for geographic differences in input prices. CMS classifies individual services into ambulatory payment classifications (APCs) on the basis of clinical and cost similarity. All services included in an APC have the same payment rate. In each APC, CMS "packages" services and items integral to the primary service to create a global payment rate. In deciding which services to package, CMS considers comments from hospitals, hospital suppliers, and others. In response to these comments, CMS pays separately for corneal tissue acquisition costs, blood and blood products, and many drugs.

Over time, CMS has expanded the number of services that are included in APC payments for associated primary services. For example, beginning in 2014, CMS added certain clinical diagnostic laboratory tests and drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or surgical procedure to the list of OPPS packaged items and services. The intent of expanded packaging was to make hospitals more cost conscious regarding the services used in an outpatient visit. In a system that packages related services under a single global payment, hospitals have a financial incentive to furnish services most efficiently and to manage their resources with maximum flexibility.[3]

TABLE 16–1

How Medicare generally pays for pain management, including prescription drugs, in the inpatient and outpatient hospital settings

Setting	Payment mechanism
Inpatient hospital	
Nondrug items and services	Part A IPPS sets one bundled payment for all items and services for each MS–DRG category*
Prescription drugs	Part A IPPS sets one bundled payment for all items and services for each MS–DRG category
Outpatient hospital	
Nondrug items and services	Part B OPPS sets one bundled payment rate for primary service plus items and services integral to the primary service for each APC category**
Prescription drugs	
Directly related and integral to the procedure or treatment	Part B OPPS sets one bundled payment rate for primary service plus items and services integral to the primary service for each APC category
Not directly related and integral to the procedure or treatment—including when the drug itself is the treatment	Part D may pay for the drug, subject to plan requirements; otherwise, beneficiary is responsible for cost

Note: IPPS (inpatient prospective payment system), MS–DRG (Medicare severity–diagnosis related group), OPPS (outpatient prospective payment system), APC (ambulatory payment classification).
*Inpatient hospitals are eligible for designated new medical services and technology payments, which are in addition to the MS–DRG payment. No pain management drugs or services are currently approved for these payments.
**Outpatient hospitals are eligible for designated new-technology APCs and pass-through payments. The only pain management drug or service currently approved for these payments is buprenorphine extended-release injections, which are used to treat opioid addiction.

Pain drugs administered during an outpatient visit may be paid under Part B or Part D. Medicare Part B covers drugs that are administered by infusion or injection in hospital outpatient departments, as well as drugs that are usually self-administered (e.g., taken orally) when they are "directly related and integral to a procedure or treatment and [are] required to be provided to a patient in order for a hospital to perform the procedure or treatment during a hospital outpatient encounter" (Centers for Medicare & Medicaid Services 2002). In these cases, the usually self-administered drug is treated as a packaged supply (Table 16-1). Usually self-administered drugs that do not meet these conditions are billed to the beneficiary and could be covered under Part D if the beneficiary is enrolled in Part D and their plan covers the drug and if other plan requirements (e.g., the hospital's pharmacy is a participating pharmacy with the plan) are met.[4]

Determining which exact drugs meet the "directly related and integral" criterion is not straightforward and is ultimately left to the discretion of individual Medicare administrative contractors (MACs).[5] CMS guidance to MACs to help them determine whether drugs should be covered under the OPPS is laid out in the *Medicare Benefit Policy Manual* (Centers for Medicare & Medicaid Services 2018d). The guidance notes that "[e]xcept for the applicable copayment, hospitals may not bill beneficiaries for these types of drugs because their costs, as supplies, are packaged into the payment for the procedure with which they are used." Examples provided include sedatives administered in the preoperative area before a procedure and antibiotic ointments applied to a surgical incision at the end of a procedure. (Pain medications are not included as an example.) Drugs that do not meet the directly related or integral to a procedure criterion and therefore are not considered a packaged supply include drugs that a patient routinely takes (e.g., insulin, hypertension medication) and those for which "the drug itself is the treatment instead of being integral or directly related to the procedure, or facilitating the performance of or recovery from a

New-technology ambulatory payment classifications and pass-through payments

The outpatient prospective payment system (OPPS) includes two design features to accommodate hospitals' adoption of innovative, expensive pain treatments. CMS assigns some new services to "new-technology" ambulatory payment classifications (APCs) based only on similarity of resource use. CMS chose to establish new-technology APCs because some services were too new to be represented in the data the agency uses to develop the initial payment rates for the OPPS. Services generally remain in these APCs for two to three years while CMS collects the cost data necessary to develop payment rates for them.[6] Each year, CMS determines which new services, if any, should be placed in new-technology APCs. Payments for new-technology APCs are not subject to budget-neutrality adjustments, so they increase total OPPS spending.

In addition to new-technology APCs, pass-through payments are another way that the OPPS accounts for new technologies. In contrast to new-technology APCs—which are payments for individual services—pass-through payments are for specific drugs, biologicals, and devices that providers use in the delivery of services. The purpose of pass-through payments is to help ensure beneficiaries' access to technologies that are too new to be well represented in the data that CMS uses to set OPPS payment rates. ■

particular procedure." Examples of excluded drugs are pain medication given to a patient going to the emergency department with pain or to a patient developing a headache while receiving chemotherapy.

CMS guidance indicates that MACs may not pay for "any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient" (Centers for Medicare & Medicaid Services 2018d). Additionally, any drugs given to the patient for continued use at home (e.g., finishing the last of a three-day supply of opioids) are not paid under Part B.

When Part B does not cover a drug administered in the outpatient setting, the hospital usually charges the patient for the drug (Centers for Medicare & Medicaid Services 2017a).[7] If the beneficiary has a Part D drug plan, the plan might pay for the drug if it is included in the plan's formulary. However, most hospital pharmacies do not participate in Medicare Part D, so beneficiaries would need to pay out of pocket for these drugs and submit a claim to their Part D drug plan for a refund. Part D plans can deny payment for the drug if they determine that the beneficiary could have reasonably obtained the drug from a participating network pharmacy (e.g., taken a dose of a drug that that was purchased from an in-network pharmacy before an outpatient hospital appointment). Finally, if the drug is covered by the beneficiary's Part D drug plan, the plan might reimburse the beneficiary only for the in-network cost for the drug (minus any deductibles, copayments, or coinsurance). The beneficiary would then pay the difference between what the hospital charged and what the plan paid in addition to any applicable deductibles, copayments, or coinsurance. If the Part D plan denies payment for a drug, the beneficiary can apply for an exception.

Drugs that are covered under the OPPS (Part B) when administered in the hospital outpatient setting fall into two categories—those that are paid for separately and those that are packaged into the APC payment rate for the primary service. In final rules regarding APC packaging in 2015 and 2018, CMS stated, "We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including *postsurgical pain management drugs* [emphasis added], to be part of the surgery for purposes of our drug and biological surgical supply packaging policy" (Centers for Medicare & Medicaid Services 2017b, Centers for Medicare & Medicaid Services 2014).

Separately payable drugs have two categories: (1) pass-through, which includes drugs that are usually, but not

always, high cost and (2) separately payable, which includes drugs that exceed a per day cost threshold ($125 in 2019) (Centers for Medicare & Medicaid Services 2018e). (See text box on new-technology APCs and pass-through payments.) Drugs can have pass-through status for two to three years. By statute, CMS is required to pay pass-through drugs at a rate of average sales price plus 6 percent (ASP + 6 percent). Manufacturers of drugs with Food and Drug Administration (FDA) approval can apply for pass-through status for new drugs or biologics whose cost is not insignificant in relation to the OPPS payments for the procedures or services associated with the new drug or biologic. The second category is non-pass-through separately payable, which includes established drugs whose costs exceed $120 per day in 2018. For this category, CMS has discretion on the payment rates and has established a rate of ASP + 6 percent for those products, unless the hospital participates in the 340B Drug Pricing Program.[8]

CMS has approved several pain management drugs for pass-through status, but none that are used exclusively for pain management currently qualify under either separately payable drug category.[9,10,11] Thus, when Part B pays for pain medications, including opioids and their alternatives, in the outpatient setting, the medications are generally treated as packaged supplies under the OPPS and not paid separately from the primary procedure or treatment.[12]

Nondrug pain management

While often more associated with chronic pain management, there are nondrug treatments for pain that hospitals can choose to employ in the inpatient and outpatient settings. For example, the Institute for Clinical and Economic Review reviewed studies of acupuncture, cognitive behavioral therapy, mindfulness-based stress reduction, and yoga and found with moderate certainty that all four yielded at least a small net health benefit for improvement in function and reduction in pain for chronic low back and neck pain (Institute for Clinical and Economic Review 2017). There may be opportunities to use nondrug pain management techniques such as these in the hospital setting for acute pain for some patients. CMS is reportedly considering the evidence for various treatment alternatives for pain, and any new findings could result in triggering a coverage determination process. Studies of postsurgery use of transcutaneous electrical nerve stimulation have shown reduction in pain intensity and analgesic use (Kerai et al. 2014). While none of these nondrug pain treatments is currently paid for individually by Medicare, hospitals can opt to provide them under bundled payments.

Incentives for prescribing opioids and non-opioid alternatives in hospital settings

Some observers have questioned whether Medicare's payment systems might create financial incentives for providers to choose opioids over non-opioid alternatives. For example, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended that "CMS review and modify rate-setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate post-surgical pain" (President's Commission on Combating Drug Addiction and the Opioid Crisis 2017). The SUPPORT Act calls on the Medicare Payment Advisory Commission to identify any such incentive specific to the Medicare IPPS and OPPS. We recognize that there are additional incentives that may have an even greater influence on clinicians' choice of pain treatments, such as effects on patient experience, length of stay, need for additional nursing services, and—most important—the management of potential risks and clinical efficacy. However, these motivations are not unique to the Medicare IPPS and OPPS, so to comply with the mandate's due date, we focused on the extent to which these payment systems introduce financial incentives.

The IPPS and OPPS payment bundles are designed to give hospitals a financial incentive to be cost conscious in selecting items and services. This incentive is balanced by Medicare's quality measurement and reporting programs along with providers' clinical expertise and professionalism. Ideally, these balanced incentives result in high-quality outcomes for patients for the best prices for beneficiaries and other taxpayers.

Analysis of opioid and non-opioid prices

As mentioned earlier, the incentive under any prospective payment system is to use the most cost-effective inputs necessary to maintain good quality. As we also mentioned,

financial incentives are only one factor in determining how to address the need for pain medications in hospital settings; decisions regarding which medications to prescribe should be patient specific and can be influenced by multiple other factors.

To better understand the extent of any systemic financial incentives that would lead clinicians in hospital settings to prescribe opioids over non-opioid alternatives, we analyzed the difference in prices between opioid and non-opioid drugs commonly used in the inpatient and outpatient hospital settings. This analysis has a key caveat: We do not know the actual prices that hospitals paid for these drugs because hospitals do not report their drug acquisition costs. Average sales prices (ASPs), which are a weighted average of manufacturers' sales price for a drug for all purchasers net of price adjustments, are not available for many of the opioid and non-opioid drugs in our study. In lieu of true acquisition costs, we examined publicly available list prices: wholesale acquisition cost (WAC) and average wholesale price (AWP). WAC is the manufacturer's list price and does not incorporate prompt-pay or other discounts; it approximates what retail pharmacies pay wholesalers for single-source drugs. AWP is used as the basis for setting payment rates to pharmacies, but it is not a true representation of actual market prices for either generic or brand drug products: It is often compared with a "sticker price." Hospital (and other) pharmacies can negotiate drug prices, especially for generic and multisource drugs, and can choose which drugs to stock within the requirements of their hospital formulary.

There are several prescribing options for both opioid and non-opioid drugs, including their route of administration (e.g., oral, intravenous) and their dosage form (e.g., tablet, capsule, solution). In addition, opioids and non-opioids can be used in conjunction with one another. These drug combinations, or "cocktails," give prescribers flexibility in the choice of drug agents to treat pain and related symptoms and can mitigate the drawbacks of individual drugs in the cocktail without unduly sacrificing drug efficacy. For example, a lower dose of an opioid can be used along with a non-opioid to reduce the risk associated with the opioid while still achieving sufficient analgesic effect. This flexibility is important in the hospital setting because opioids are more often indicated for acute, severe pain than many non-opioid alternatives. While there are some recent studies that suggest similar analgesic effects of opioid and non-opioid drugs even for some cases of moderate to severe pain, it is not clear that non-opioid alternatives can or should replace opioids for all cases of acute, severe pain (Hartford et al. 2019). The flexibility of drug cocktails also allows prescribers to vary the mix of drugs included over the course of a hospital stay. For example, immediately following a surgery, the cocktail could include a higher ratio of opioids than non-opioids. This ratio could shift in the days leading up to discharge.

The analysis includes the following pain drug categories:

- ***Opioids (or full agonist opioids)*** act by attaching to and activating opioid receptors on nerve cells in the brain, spinal cord, gastrointestinal tract, and other organs. Opioids mimic the effects of naturally occurring endorphins in the body; the resultant spike in dopamine not only reduces the perception of pain but also can manufacture a powerful sense of well-being and pleasure by affecting the brain's limbic reward system. Examples of full agonists include heroin, oxycodone, methadone, hydrocodone, morphine, and opium.
- ***Opioid agonists/antagonists*** are a heterogeneous group of drugs with moderate to strong analgesic activity comparable with that of the full agonist opioids but with a limited effective dose range. In general, opioid agonists/antagonists have relatively lower physical dependence potentials than full agonist opioids. The group includes drugs that act as agonists or partial agonists at one receptor and as antagonists at another (e.g., pentazocine, butorphanol, nalbuphine) and drugs acting as partial agonists at a single receptor (e.g., buprenorphine).
- ***Nonsteroidal anti-inflammatory drugs (NSAIDs)*** reduce inflammation but are not related to steroids, which also reduce inflammation. NSAIDs work by reducing the production of chemicals that promote inflammation, pain, and fever.
- ***Additional non-opioid pain relievers and other drugs*** that do not fall under the NSAID category are included in the analysis. These drugs can be used alone or in conjunction with others to address pain (e.g., sedatives, neurologic agents). The following additional drug categories are included in the analysis:
  - ***Neurologic agents*** are used to treat certain types of neuropathic pain (nerve pain).
  - ***Sedatives*** are used to induce relaxation and sleep.

TABLE 16–2 **List prices for pain medications commonly used in hospital settings, 2017**

Pain drug group	Number of options with list prices less than $1 per dose	Share of commonly used options where list price is available	WAC list price per dose	
			Minimum	Maximum
Opioids	10	31%	$0.05	$1,361.16
Opioid agonists/antagonists	0	0	2.27	62.33
NSAIDs and other non-opioid pain relievers	27	47	0.02	64.80
Neurologic agents	2	67	0.43	6.00
Sedative agents	8	80	0.05	23.37
Musculoskeletal therapy agents	1	13	0.37	405.00
Ophthalmic agents	2	50	0.65	581.67
General anesthetics	0	0	2.59	18.42*
Local anesthetics	5	26	0.05	738.47

Note: WAC (wholesale acquisition cost), NSAID (nonsteroidal anti-inflammatory drug). Options include unique combinations of drugs, routes of administration, and dosage forms (e.g., acetaminophen oral capsule, fentanyl citrate injection solution).
*List price marked with an asterisk uses average wholesale price in lieu of unavailable WAC.

Source: MedPAC summary of Acumen LLC analysis of Medi-Span data (copyright 2017), Clinical Drug Information LLC.

- ***Musculoskeletal therapy agents*** are muscle relaxers and are used to treat muscle symptoms, such as spasm, pain, and stiffness.
- ***Ophthalmic agents*** are used to prevent or treat inflammation and provide analgesia after cataract and other eye surgery.

- ***General and local anesthetics*** are included because clinicians have the option to use these in the hospital setting to reduce or eliminate the use of other pain medications (e.g., using a local anesthetic during recovery following a surgical procedure on a limb).

Because the drugs included in our analysis can be prescribed using different dosages depending on unique patient needs, prices for each drug were standardized for a typical midrange dose for a patient of a specified weight.[13] This standardization allows comparisons across drug options. Because we found WAC and AWP price patterns to be similar, we present WAC alone for brevity.

Opioids and their alternatives are available at overlapping price ranges

Analysis of Medi-Span data (copyright 2017), provided by Clinical Drug Information LLC, shows that the ranges of list prices for opioids and their alternatives overlap (Table 16-2). The menus of opioids and non-opioids that are commonly used in hospital settings both include options that cost less than $1 per dose. Specifically, there are 10 commonly used opioid options combining drug, route of administration, and dosage form (e.g., fentanyl citrate injection solution) that cost less than $1 per dose. The lowest list price is $0.05 per dose, for morphine sulfate intravenous solution. There are 27 commonly used NSAIDs and other non-opioid pain reliever options combining drug, route of administration, and dosage form (e.g., acetaminophen oral capsule) that cost less than $1 per dose. The lowest list price is $0.02 per dose for aspirin oral tablet. The commonly used drug groups neurologic agents, sedative agents, musculoskeletal therapy agents, ophthalmic agents, and local anesthetics all include an option of a drug, route of administration, and dosage form combination that costs less than $1 per dose.

All of the pain drug groups commonly used in hospital settings include combinations of drug, route of administration, and dosage form with high—and sometimes very high—list prices. The highest list price among commonly used opioid combinations of drug, route of administration, and dosage form is $1,361.16 a dose for fentanyl citrate nasal solution (Table 16-3, p. 462). The highest list price among commonly used NSAIDs and other non-opioid pain reliever options combining

TABLE 16–3

Publicly available wholesale acquisition cost list prices for opioids and opioid agonists/antagonists commonly used in the inpatient and outpatient hospital settings, 2017

Drug, route of administration, and dosage form	Median list price per dose
Opioid pain relievers	
Alfentanil injection injectable	$10.73
Codeine sulfate	
Oral solution	13.40
Oral tablet	1.82
Fentanyl citrate	
Sublingual lozenge on a handle	15.76
Sublingual tablet	133.31
Injection solution	0.52
Injection solution cartridge	1.30
IV solution	N/A
IV solution prefilled syringe	2.96*
Nasal solution	1,361.16
Hydromorphone HCl	
Injection solution	5.40
Injection solution reconstituted	N/A
Levorphanol tartrate oral tablet	42.71
Meperidine HCl injection solution	14.08
Methadone HCl	
Injection solution	18.72
Oral concentrate	0.09
Oral solution	1.37
Oral tablet	0.35
Oral tablet soluble	0.19
Morphine sulfate	
Injection solution	1.78
Injection solution	1.78
Intramuscular device	N/A
IV solution	0.05
Oral solution	0.86
Oral tablet	0.55
Rectal suppository	0.08
Morphine sulfate pentahydrate epidural suspension	6.87
Oxycodone HCl	
Oral capsule	5.88
Oral concentrate	5.63
Oral solution	18.97
Oral tablet	0.70
Oxymorphone HCl injection solution	N/A
Remifentanil HCl IV solution reconstituted	4.38
Sufentanil citrate IV solution	101.75
Tapentadol HCl oral tablet	14.36
Tramadol HCl	
External cream	7.83
Oral suspension reconstituted	N/A
Oral tablet	0.13
Opioid agonists/antagonists	
Buprenorphine HCl	
Sublingual film	6.61
Injection solution	13.87
Subcutaneous implant	N/A
Butorphanol tartrate	
Injection solution	4.58
Nasal solution	4.51
Nalbuphine HCl injection solution	2.27
Pentazocine lactate injection solution	62.33

Note: IV (intravenous), HCl (hydrochloride), N/A (not available). All national drug codes (NDCs) for each drug were matched to wholesale acquisition cost (WAC) list prices that were standardized in terms of a single unit (e.g., 1 mg/ml, 1 mcg, 1 percent). If the normal dosage of the drug included a range (e.g., 200–300 mg), these unit prices were then standardized in terms of the midpoint of a drug's normal dosage. If the normal dosage included a reference to kilograms (e.g., 1 ug/kg/min), a standard patient weight of 71.4 kg was used to determine the total normal dosage. NDCs with percentage units of measure (UOMs) were converted by checking the package-size UOM in Medi-Span. If a package had grams or milliliters as the UOM, the drug ingredient strength was multiplied by 10 and the NDC's UOM was changed to match the package-size UOM. If there were multiple UOMs associated with a combination, the price is reported in terms of a single unit because of concerns about unit conversion to the normal dose.
*List prices marked with an asterisk use average wholesale price in lieu of unavailable WAC.

Source: Acumen LLC analysis of Medi-Span data (copyright 2017), Clinical Drug Information LLC.

drug, route of administration, and dosage form is $64.80 a dose for diclofenac potassium oral packet (Table 16-4, p. 464). Higher list prices appear to be determined more (but not exclusively) by the route of administration and dosage form than by the drug ingredient. For example, acetaminophen is available in 12 different route of administration–dosage form combinations with at least one list price less than $2 per dose. The 2017 list price for the one acetaminophen intravenous solution option is not publicly available. However, the price for a midrange dose (i.e., using the same methodology applied in Table 16-2, p. 461; Table 16-3, p. 462; and Table 16-4, pp. 464–465) in

2014 was reportedly significantly more expensive at about $26.00 (Sanghera 2018). The five highest priced options combining drug, route of administration, and dosage form (all with list prices greater than $300) include an intravenous solution reconstituted, an injection suspension, a nasal solution, an ophthalmic solution, and a local anesthetic injection kit.

Hospital systems have responded in various ways to concerns about opioids and the differences in drug prices for pain treatment. For example, Geisinger Health System implemented the ProvenRecovery pilot in June 2017, which focuses on supporting nutrition, managing pain without the use of opioids, and promoting the postsurgery mobility of patients (Geisinger 2018, Johnson 2018). The pharmaceutical approach is opioid avoidant or, in some cases, opioid free, by using a multimodal pain management combination of non-opioid alternatives, such as acetaminophen, ibuprofen, gabapentin, ketamine, and lidocaine (Reed 2018). The program reportedly has driven an 18 percent decrease in opioid usage. While the use of multiple non-opioid alternatives (e.g., intravenous acetaminophen) may increase pharmaceutical spending, under Medicare's prospective payment systems these costs may be offset by reducing length of stay. Geisinger announced that the pilot resulted in 50 percent reductions in length of stay for neurosurgery and colorectal surgery patients. Earlier discharges accounted for an average savings of $4,556 per case for colorectal surgery patients.

As another example of hospitals responding to differences in pain treatment drug prices, Chandler Regional Medical Center in Arizona focused specifically on the use of intravenous versus oral acetaminophen (Prince and Dungy 2015). In 2010, the FDA approved the first intravenous route of administration for acetaminophen (Waknine 2010). In 2014, Mallinckrodt Pharmaceuticals purchased the original manufacturer, Cadence Pharmaceuticals Inc., and increased the list price by 140 percent from $14.60 to $35.05 for each 1-gram vial (Sanghera 2018). Chandler conducted an internal retrospective study comparing postoperative use of intravenous versus oral acetaminophen for hip replacement and knee replacement patients. Lengths of stay for both groups were similar, and, as a result, Chandler adopted guidelines that called for greater use of oral acetaminophen, which led to saving about 45 percent on the drug overall.

There is no clear indication that Medicare's IPPS or OPPS provides systematic payment incentives that promote the use of opioid analgesics over non-opioid analgesics. Both opioids and non-opioids are available at a range of list prices; there are options for either type of drug that cost less than $1 per dose. There are some non-opioid options combining drug, route of administration, and dosage form that are much more expensive, but that is also true of opioid drugs. Hospitals that take on additional costs by selecting more expensive non-opioid drugs (e.g., intravenous acetaminophen) for clinical reasons can mitigate those costs by also adopting best practices and shifting patients to cheaper options combining route of administration and dosage form (e.g., oral and rectal acetaminophen) on a recommended schedule. Additionally, when hospitals implement prescribing protocols that rely on greater use of an expensive drug option, they can negotiate with their group purchasing organization for a better volume discount on the drug. Note that the prices included in our study are publicly available list prices; hospitals' true acquisition costs are lower, and the difference between list and acquisition prices presumably varies by drug. Finally, hospitals can partially or more than fully offset the cost of more expensive drug options if those options lower other costs by reducing length of stay or the need for other drugs (e.g., antiemetics) or nursing services.

Medicare monitoring of opioid use through claims and other data

CMS monitors opioid use in the Part D program through claims and other data. The agency does not operate similar tracking programs in Part A and Part B. CMS has required Part D plan sponsors to operate drug utilization management, quality assurance, and medication therapy management programs since Part D's inception in 2006. In response to concerns about the opioid epidemic, CMS implemented an opioid overutilization policy effective January 1, 2013, that called on Part D plan sponsors to take several steps to monitor their enrollees' opioid use to reduce overuse while maintaining enrollees' access to needed pain medications. The overutilization policy requires Part D plan sponsors to maintain appropriate plan-level claim controls at point of sale (POS) for opioids, including safety edits (electronic checks at the pharmacy that prompt the pharmacist to check with the prescriber before dispensing as necessary) and quantity limits; retrospective drug utilization review to identify beneficiaries at high risk of an adverse event because of opioids; case management with identified high-risk

TABLE 16–4

Publicly available wholesale acquisition cost list prices for non-opioids commonly used in the inpatient and outpatient hospital settings, 2017

Drug, route of administration, and dosage form	Median list price per dose
NSAIDs and other non-opioid pain relievers	
Acetaminophen	
IV solution	N/A
Oral capsule	$0.13
Oral elixir	0.13
Oral gel	0.84
Oral liquid	1.04
Oral packet	0.10
Oral solution	1.70
Oral suspension	1.04
Oral syrup	1.32
Oral tablet	0.05
Oral tablet, chewable	0.38
Oral tablet, disintegrating	0.39
Rectal suppository	1.05
Aspirin	
Oral tablet	0.02
Oral tablet, chewable	0.23
Oral tablet, disintegrating	N/A
Rectal suppository	0.19
Celecoxib oral capsule	1.48
Choline magnesium trisalicylate	
Oral liquid	2.89
Oral tablet	0.51
Clonidine HCl	
Epidural solution	0.98
Oral tablet	0.08
Diclofenac oral capsule	9.31
Diclofenac potassium	
Oral capsule	22.08
Oral packet	64.80
Oral tablet	1.31
Diclofenac sodium IV solution	N/A
Diflunisal oral tablet	1.21
Etodolac	
Oral capsule	0.83
Oral tablet	0.68
Fenoprofen calcium	
Oral capsule	10.36
Oral tablet	2.26
Ibuprofen	
External cream	31.07
IV solution	14.56
Oral capsule	0.36
Oral kit	N/A
Oral suspension	1.68
Oral tablet	$0.14
Oral tablet, chewable	1.12
Indomethacin	
Oral capsule	0.18
Oral suspension	N/A
Rectal suppository	N/A
Ketoprofen	
Cream	15.51
External cream	0.07
Oral capsule	0.36
Meclofenamate sodium oral capsule	4.64
Mefenamic acid oral capsule	13.93
Meloxicam	
Oral capsule	24.48
Oral suspension	7.20
Oral tablet	0.05
Nabumetone oral tablet	0.67
Naproxen	
External cream	17.45
Oral suspension	28.20
Oral tablet	0.14
Naproxen sodium	
Oral capsule	0.31
Oral tablet	0.17
Oxaprozin oral tablet	3.97
Piroxicam oral capsule	1.87
Salsalate oral tablet	0.97
Sulindac oral tablet	0.21
Tolmetin sodium	
Oral capsule	2.16
Oral tablet	2.08
Ziconotide acetate intrathecal solution	5.73
Anticonvulsant, psychotherapeutic, and neurological agents	
Gabapentin	
External cream	N/A
Oral capsule	0.43
Oral solution	6.00
Oral suspension	N/A
Oral tablet	0.87

TABLE 16–4

Publicly available wholesale acquisition cost list prices for non-opioids commonly used in the inpatient and outpatient hospital settings, 2017 (cont.)

Drug, route of administration, and dosage form	Median list price per dose
Antihistamines, hypnotics, sedatives, sleep disorder agents	
Diphenhydramine HCl	
Injection solution	0.95
Oral capsule	0.05
Oral elixir	2.29
Oral liquid	0.30
Oral strip	0.81
Oral suspension reconstituted	23.37
Oral syrup	0.10
Oral tablet	0.07
Oral tablet, chewable	0.72
Oral tablet, disintegrating	0.30
General anesthetics	
Ketamine HCl	
Injection solution	2.59
IV solution prefilled syringe	18.42*
Local anesthetics, dermatologicals, and ophthalmic agents	
Bupivacaine injection suspension	335.06
Bupivacaine HCl	
Injection kit	738.47
Injection solution	5.57
Chloroprocaine HCL injection solution	29.30
Lidocaine	
External aerosol	5.70*
External cream	17.38
External gel	7.58
External kit	10.31
External lotion	N/A
External ointment	59.26
External patch	1.57
Lidocaine HCl	
External cream	0.08
External gel	0.05
External kit	323.10
External liquid	2.72
External lotion	0.22
External ointment	41.58
External solution	6.31
Mepivacaine HCl injection solution	2.98
Prilocaine HCl injection solution	N/A
Ropivacaine HCl	
Epidural solution	N/A
Injection solution	0.13
Tetracaine HCl	
Injection solution	N/A
Ophthalmic solution	0.71
Musculoskeletal therapy agents	
Baclofen	
Intrathecal solution	11.83
Intrathecal solution, prefilled syringe	12.72
Oral suspension	1.76
Oral tablet	0.37
Dantrolene sodium	
IV solution reconstituted	405.00
IV suspension reconstituted	N/A
Oral capsule	3.06
Ophthalmic agent analgesics	
Flurbiprofen sodium ophthalmic solution	581.67
Ketorolac tromethamine	
Injection kit	N/A
Injection solution	2.16
Intramuscular solution	0.90
Oral tablet	0.65

Note: NSAID (nonsteroidal anti-inflammatory drug), IV (intravenous), HCl (hydrochloride), N/A (not available). All national drug codes (NDCs) for each drug were matched to wholesale acquisition cost (WAC) list prices that were standardized in terms of a single unit (e.g., 1 mg/ml, 1 mcg, 1 percent). If the normal dosage of the drug included a range (e.g., 200–300 mg), these unit prices were then standardized in terms of the midpoint of a drug's normal dosage. If the normal dosage included a reference to kilograms (e.g., 1 ug/kg/min), a standard patient weight of 71.4 kg was used to determine the total normal dosage. NDCs with percentage units of measure (UOMs) were converted by checking the package-size UOM in Medi-Span. If a package had grams or milliliters as the UOM, the drug ingredient strength was multiplied by 10 and the NDC's UOM was changed to match the package-size UOM. If there were multiple UOMs associated with a combination, the price is reported in terms of a single unit because of concerns about unit conversion to the normal dose. Prices are reported in terms of a single unit for the ropivacaine HCl injection solution and ropivacaine HCl epidural solution combinations because of concerns about the normal dose of UOMs.
*List prices marked with an asterisk use average wholesale price in lieu of unavailable WAC.

Source: Acumen LLC analysis of Medi-Span data (copyright 2017), Clinical Drug Information LLC.

beneficiaries' prescribers followed by beneficiary-specific POS edits to prevent Part D coverage of opioid overuse, if necessary; and data sharing between Part D plan sponsors regarding identified beneficiary opioid overutilization (Centers for Medicare & Medicaid Services 2012). CMS is planning additional opioid safety steps that will begin in 2019.

Overutilization Monitoring System

In July 2013, CMS added the Medicare Part D Overutilization Monitoring System (OMS) to ensure that Part D plan sponsors implement the opioid overutilization policy effectively (Centers for Medicare & Medicaid Services 2013b). Through the OMS, CMS analyzes prescription drug event (PDE) data to identify beneficiaries at risk for opioid or other drug overuse. PDE data are a summary record that prescription drug plan sponsors must submit every time an enrollee fills a prescription under Medicare Part D. The PDE data are not the same as individual drug claim transactions, but are summary extracts using CMS-defined standard fields (Centers for Medicare & Medicaid Services 2013c).

The other drugs included in the OMS are high-dose acetaminophen and concurrent use of benzodiazepines with opioids (added in 2016) (Centers for Medicare & Medicaid Services 2018a).[14] In a 2019 call letter, CMS announced that the agency would also add high-dose gabapentin or pregabalin used concurrently with opioids. (All prescription drug products that contain acetaminophen include in their labeling a black box warning highlighting the potential for severe liver injury and death.[15] Benzodiazepines and gabapentin are contraindicated for patients taking opioids because they increase the risk of possible complications, including overdose.) CMS also announced that it would perform additional analyses and consider enhancements to the OMS in the future to track information on OMS potential opioid overutilizers who concurrently use other potentiator drugs, such as muscle relaxants (e.g., carisoprodol) or sedative hypnotics (e.g., zolpidem, zalepron, and eszopiclone).[16]

CMS does not monitor for the potential overuse of other opioid alternatives (Centers for Medicare & Medicaid Services 2018b). CMS notes that many non-opioid drug alternatives are offered over the counter and thus would not result in PDE data. Nondrug alternatives would also not be captured by prescription drug plan data. Nondrug alternatives would only be identifiable in Medicare Advantage prescription drug plan data to the extent that the plans covered these options as benefits (e.g., physical therapy, mental health services) and would be missing for those not covered (e.g., therapeutic massage, acupuncture).

Any beneficiaries identified as potential overutilizers through these analyses are included in reports sent to Part D plan sponsors through the Patient Safety Analysis Website.[17,18] Hospice and cancer patients are excluded from the opioid utilizer and OMS criteria counts. Patients in long-term care facilities or receiving palliative or end-of-life care are also excluded beginning in 2019 (Centers for Medicare & Medicaid Services 2018a). Reports are issued every quarter based on PDE data from the prior two quarters. Part D plan sponsors are required to review the reports and respond to CMS within 30 days, describing the status of each beneficiary's case. Data shared with individual plans are confidential/secure; aggregated data are released occasionally by CMS (e.g., in notices, annual conferences). CMS does not publish an annual report on potential overutilizers (e.g., addressed to the public or to the Congress).

The OMS has achieved some success. CMS reports that from 2011 to 2017 the share of Part D enrollees who were prescribed opioids decreased from 32 percent to 28 percent (Centers for Medicare & Medicaid Services 2018a). In addition, over this same period, the share of enrollees identified as opioid utilization outliers according to OMS criteria fell from 0.29 percent to 0.05 percent.

As required by the Comprehensive Addiction and Recovery Act (CARA) of 2016, CMS finalized through rulemaking the framework under which Part D plan sponsors may adopt drug management programs (DMPs) beginning January 1, 2019, for beneficiaries who are at risk of misusing or abusing frequently abused drugs. The rule codified many aspects of the retrospective Part D Opioid Drug Utilization Review (DUR) Policy and the OMS, with adjustments as needed to comply with CARA, by integrating them into the DMP provisions (Centers for Medicare & Medicaid Services 2018f).

Quality measures

CMS also uses quality measures to track trends in opioid overuse across the Medicare Part D program and drive performance improvement among plan sponsors. These measures include publicly available display measures and confidential patient safety reports that are sent to plan sponsors.

Display measures, which are not part of the star ratings used to assess quality performance in Medicare Advantage and Part D plans, are available at CMS.gov (Centers for Medicare & Medicaid Services 2019b). These measures may include ones that are transitioned out of inclusion in the star ratings, new measures that are being tested before inclusion in the star ratings, or measures displayed solely for informational purposes (Centers for Medicare & Medicaid Services 2018a). Organizations and sponsors have the opportunity to preview the data for their display measures before release on CMS's website. Poor scores on display measures may reveal underlying compliance and performance issues that are subject to enforcement actions by CMS.

Since 2016, Part D plan sponsors have received monthly patient safety reports based on the Pharmacy Quality Alliance (PQA) opioid measures.[19] CMS communicates with plans about their performance on these quality measures, including sharing information about individual beneficiaries identified. Plan sponsors with the lowest rating on each measure are expected to report actions they will take to improve performance (Centers for Medicare & Medicaid Services 2018a). Sponsors can use the reports to supplement their drug utilization review programs and address potential overuse of opioids across a population broader than that addressed by the OMS. CMS expects sponsors to routinely monitor these data to compare their performance with overall averages and assess their progress in reducing the number of beneficiaries using high doses of opioids, with or without multiple providers and pharmacies.

CMS's Part D opioid quality measures include three PQA measures that examine multiprovider and high-dosage opioid use among individuals 18 years and older without cancer and not in hospice care, plus one PQA measure of concurrent use of opioids and benzodiazepines (Centers for Medicare & Medicaid Services 2018a). Specifically, the following measures are used:

- ***Measure 1—***Use of Opioids at High Dosage in Persons without Cancer. The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine milligram equivalents (MMEs) for 90 consecutive days or longer.
- ***Measure 2—***Use of Opioids from Multiple Providers in Persons without Cancer. The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids from 4 or more prescribers *and* 4 or more pharmacies.
- ***Measure 3—***Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer. The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 mg MMEs for 90 consecutive days or longer *and* who received opioid prescriptions from 4 or more prescribers *and* 4 or more pharmacies.
- ***PQA's Concurrent Use of Opioids and Benzodiazepines—***This measure assesses the share of individuals 18 years and older with concurrent use of opioids and benzodiazepines.[20]

All three overuse measures are included in the patient safety reports sent to plan sponsors. CMS announced that the concurrent use of opioids and benzodiazepines would be added to patient safety reports for the 2018 measurement year. In addition, the third overuse measure will be added to the 2019 Part D display measures (using 2017 data), and the concurrent use measure will be added for 2021 (2019 data) and 2022 (2020 data). The agency will consider the concurrent use measure for the 2023 star ratings (2021 data) pending rulemaking.

Medicare Part D opioid prescribing mapping tool

In addition to tracking beneficiaries' use of opioids, CMS uses PDE data to monitor clinicians' opioid prescribing patterns. The results are publicly available on the CMS website through the Medicare Part D opioid prescribing mapping tool that shows geographic comparisons at the state, county, and ZIP code levels of Medicare Part D opioid prescriptions. The mapping tool presents Medicare Part D opioid prescribing rates for 2016 as well as the change in opioid prescribing rates from 2013 to 2016 (Centers for Medicare & Medicaid Services 2019a). The tool does not identify or include information on individual beneficiaries but, rather, identifies individual clinicians. The analysis is from the prescriber perspective rather than the beneficiary perspective and is not designed to indicate the quality or appropriateness of the opioid prescriptions; unlike the OMS analysis, opioid prescriptions to hospice and cancer patients are included.

Food and Drug Administration opioid policy and drug surveillance programs

The Food and Drug Administration (FDA) published its Strategic Policy Roadmap in January 2018 that summarizes the agency's efforts to address opioid misuse along with other policy objectives (Food and Drug Administration 2018). The Roadmap indicates that the FDA's policy priorities are to help ensure that patients are prescribed opioids only when their use is clinically indicated and that prescriptions are for appropriately limited dosages and durations. The FDA will also focus on efforts to facilitate treatment options and the development of therapies to address addiction as a disease, including getting more people in need access to medication-assisted treatment (MAT) for addiction, involving the use of medications in combination with counseling and behavioral therapies.

The FDA is also seeking increased development and use of opioid drugs with improved formulations less likely to lead to overuse; alternative drugs and devices that treat pain with less risk of addiction; and better treatments for addiction, including both opioid agonists—drugs that mimic the effects of naturally occurring endorphins in the body and produce an opiate effect by interacting with specific receptor sites (e.g., heroin, oxycodone, methadone, hydrocodone, morphine, opium)—and antagonists—drugs that block the action of the agonist and have an inverse effect (e.g., naloxone, naltrexone). The FDA also plans to foster wider adoption of MAT by addressing the stigma associated with use of these drugs.

Additionally, the FDA will strengthen its enforcement activities that target those who unlawfully market or distribute controlled substances and other unapproved drugs. The agency will also increase efforts aimed at the interdiction of opioids being illegally shipped into the United States.

(continued next page)

Policy options for tracking opioid use in hospital settings

Given concerns about the opioid crisis, should CMS track opioid use in hospital inpatient and outpatient settings? If so, what lessons learned from CMS's tracking of opioid use in Part D could be applied to similar efforts in Part A and Part B? Reasons for undertaking a tracking program include the severity of the opioid epidemic and the gap in knowledge about the degree to which Medicare beneficiaries are exposed to opioids while in the hospital. Balanced against these reasons are the current lack of claims and other data infrastructure to support a tracking program and questions about how to interpret the appropriateness of opioid prescriptions identified by a tracking program.

Public concerns have largely focused on longer term use of opioids for chronic pain. Yet the Centers for Disease Control and Prevention's (CDC) recommendation to limit opioids for acute pain to three days or less clearly has implications for opioid use in the inpatient setting (Dowell et al. 2016).[21] The average length of stay for Medicare fee-for-service beneficiaries in 2016 was 4.5 days (Medicare Payment Advisory Commission 2018). The recommendation may play a role in the outpatient setting too since patients may begin an opioid course during their outpatient visit and then complete the course at home. Both settings introduce the risk of beneficiary confusion about transitioning their medication regime begun in the hospital setting postdischarge, as well as a lack of coordination between hospital and community-based prescribers. Clinical evidence cited by the CDC review found that opioid use for acute pain is associated with long-term opioid use and that a greater amount of early opioid exposure is associated with greater risk of long-term use.

Other organizations have also raised concerns and issued guidance about opioid prescribing in hospital settings. For example, in 2015 the Society of Hospital Medicine (SHM) published guidelines on hospital-based opioid prescribing that reviewed best practices for safe opioid

Food and Drug Administration opioid policy and drug surveillance programs (cont.)

Postmarketing surveillance programs

The FDA maintains a system of postmarketing surveillance and risk assessment programs to identify adverse events that were not identified during drug testing before approval. Postmarketing surveillance monitors for adverse events such as adverse reactions and poisonings. The FDA uses this information to update drug labeling, to send informative letters to clinicians, and, on rare occasions, to reevaluate an approval or marketing decision.

The FDA Adverse Event Reporting System (FAERS) is a computer database designed to support the FDA's postmarketing surveillance programs for all approved drug and therapeutic biologic products. FAERS contains adverse event reports, medication error reports, and product quality complaints resulting in adverse events that were submitted to the FDA. Health care professionals, consumers, and manufacturers can voluntarily submit reports to FAERS. If a drug manufacturer receives a report from a health care professional or consumer, it is required to send the report to the FDA.

The FAERS data, while useful, have several limitations. They are not complete; the FDA does not receive reports for every adverse event or medication error that occurs with a product. It may also overstate or misstate potential problems. The FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Thus, FAERS data serve as a source of information for further investigation where warranted. Reports in FAERS are evaluated by the FDA's clinical reviewers. If there is sufficient cause for concern about a potential safety issue, further evaluation can include conducting studies on large databases such as the FDA's national electronic system Sentinel, which includes large amounts of electronic health care data from electronic health records, insurance claims data, and registries from a diverse group of data partners. ■

use, including assessing risks; selecting the optimal dose, route, and frequency; and monitoring patients on opioids (Frederickson et al. 2015). In 2018, SHM updated its guidance to state that "SHM recommends that clinicians limit the use of opioids to patients with 1) severe pain or 2) moderate pain that has not responded to non-opioid therapy or where non-opioid therapy is contraindicated or anticipated to be ineffective" (Herzig et al. 2018). In addition, in 2017 the Colorado Chapter of the American College of Emergency Physicians published guidelines on opioid prescribing in emergency departments, stating that opioids "should be avoided whenever possible and, in most cases, initiated only after other modalities of pain control have been trialed" (Colorado Chapter of the American College of Emergency Physicians 2017).

Together, these recommendations suggest that by monitoring opioid use only in the Part D program, Medicare is missing a substantial opportunity to prevent opioid-related harm to beneficiaries. Importantly, other federal agencies besides CMS have jurisdiction over some aspects of opioid use, such as the FDA, CDC, and the Substance Abuse and Mental Health Services Administration, but these agencies also lack programs that track opioid utilization in the hospital setting (see text box on the FDA's opioid policy and drug surveillance programs). States have taken a role through the use of prescription drug monitoring programs (PDMPs) with electronic databases that track a state's controlled substance prescriptions. Currently, 49 states, the District of Columbia, and Guam each operate a PDMP (Prescription Drug Monitoring Program Training and Technical Assistance Center 2018a). PDMPs collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and certain other dispensers, including hospital outpatient departments. Hospital inpatient pharmacies are not required to report (Prescription Drug Monitoring Program Training and Technical Assistance Center 2018b). Pharmacies submit these data to state PDMPs at varying intervals—ranging from monthly to daily or even in real time (Centers for Disease Control and Prevention 2017). The timeliness of data submission affects the utility of the databases' tracking. Some states have implemented policies

that require clinicians to check a state PDMP before prescribing certain controlled substances and to limit prescribing to certain circumstances (Centers for Disease Control and Prevention 2017).

There are compelling patient safety and public health reasons for Medicare to track the use of opioids and non-opioid alternatives in hospital settings. If policymakers were to consider options for tracking pain treatment in hospitals, there are at least three options for implementing such a program:

- ***Require PDE-type reporting—***If Medicare were to undertake an opioid monitoring program in Part A and Part B, structural differences would require CMS to adapt its current monitoring program under Part D to monitor operations under Part A and Part B. Medicare relies on Part D plan sponsors to report PDE data representing the claims between pharmacies and the plans. CMS uses a contractor to analyze the PDE data to identify potentially at-risk beneficiaries and prescribers with outlier prescribing patterns. It also relies on the plan sponsors to use the analytic results along with plan data to implement drug management programs, such as POS edits, case management, outreach and education to enrollees, and clinical contact with prescribers. While there are no drug plan sponsors in Part A and Part B like there are in Part D, prescribing clinicians or hospitals could be required to report specific summary information (similar to the PDE data) about the pain management drugs to MACs or other contractors for analysis.

- ***Include drugs in Part A and Part B claims—***These claims currently do not include complete information on the pain management drugs paid for under the IPPS and OPPS as packaged supplies. CMS could take steps to incorporate these data into the claims and then require hospitals to include information about all pain management drugs used. This option would require decisions about how best to proceed (e.g., pain management drugs could continue to be packaged but identified on the claim through a modifier) and would likely require a multiyear effort to implement. Some entity (e.g., MACs or another contractor) would then need to extract the opioid information from the claims for analysis.

  Both the PDE-type and claims reporting options would require new efforts by hospitals. While to date Medicare has not called on hospitals to provide information about all pain drugs prescribed for beneficiaries, other payers do. Given that hospitals provide charge information for individual drugs when billing these payers or uninsured patients, internal tracking mechanisms already exist. Considering the urgency of the opioid epidemic and the preference for program oversight, policymakers may wish to direct hospitals to draw on their existing internal tracking mechanisms to report information about drug use for pain to Medicare as they do for other payers.

- ***Link Part D opioid use to hospitals responsible for initiation—***If policymakers were concerned about introducing undue burden on hospitals by requiring either PDE-type or claims reporting of pain management drug use, they could opt for an indirect method of associating a beneficiary's opioid use with the hospital that first prescribed it. This method offers the advantage of drawing on existing PDE data but has the disadvantages of potentially delaying identification (e.g., beneficiaries may not fill a Part D opioid prescription for months or years following initial use in a hospital setting) and identifying linkages between eventual Part D utilization and initial hospital introduction of opioids that would be open to interpretation and challenge (e.g., a hospital identified as responsible could turn out to represent the second use of opioids following an initiation years earlier or could have used opioids for a limited number of days and discharged the patient with appropriate follow-up care instructions that were then superseded by a community-based physician).

Another key difference from Part D is that once any Part A or Part B opioid use data are analyzed, policymakers would need to determine to whom and how the results should be communicated back to hospitals and their prescribing physicians. In Part D, plan sponsors often have a contractual relationship with prescribers and are expected to educate and communicate with them about plan policies. There are no drug plan sponsors to take on this role in Part A or Part B. Thus, policymakers would need to determine whether CMS, MACs, or other contractors should communicate analytic results with prescribers, hospitals, or both and what, if any, additional steps beyond communication and education should be taken. ■

Endnotes

1 Medicare makes extra payments for "outlier cases," which are extraordinarily costly, producing losses that may be too large for hospitals to offset.

2 Any physician services provided during the stay by a physician who is not an employee of the hospital are billed separately from hospital inpatient charges. Medicare Part B pays for these services under the physician fee schedule.

3 "Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient." (For additional detail, see Centers for Medicare & Medicaid Services 2016, Centers for Medicare & Medicaid Services 2015, Centers for Medicare & Medicaid Services 2014, Centers for Medicare & Medicaid Services 2013a, Centers for Medicare & Medicaid Services 2007, Centers for Medicare & Medicaid Services 2000.)

4 For example, Medicare would not treat as packaged supplies any drugs that are given to a patient for continued use at home after leaving the hospital. Another example would be a situation in which a patient who is receiving an outpatient chemotherapy treatment develops a headache. Any medication given to the patient for the headache would not meet the conditions necessary to be treated as a packaged supply. Similarly, if a patient who is undergoing surgery needs his or her daily insulin or hypertension medication, the medication would not be treated as a packaged supply.

5 MACs are private companies that have been awarded CMS contracts to process Medicare Part A and Part B medical claims or durable medical equipment claims for Medicare fee-for-service beneficiaries.

6 In the 2017 final rule, CMS adopted a policy to allow for quarterly expiration of pass-through payment status for devices, beginning with newly approved pass-through payment devices in 2017, to afford a pass-through payment period that is as close to a full three years as possible for all pass-through payment devices (Centers for Medicare & Medicaid Services 2016).

7 The Department of Health and Human Services Office of Inspector General permits hospitals to waive costs owed by Medicare beneficiaries, including cost-sharing amounts, without violating the federal anti-kickback statute, in limited circumstances. Under the criteria for waiving costs: (1) the costs waived must be only for noncovered self-administered drugs used in outpatient settings, (2) hospitals must uniformly apply their waiver policy, (3) hospitals may not advertise their waiver policy, and (4) hospitals must not claim the waived amounts as bad debt or shift the burden of these costs to other payers or individuals (Office of Inspector General 2015).

8 Under the 340B program, certain providers known as 340B hospitals ("covered entities") can obtain discounted prices on covered outpatient drugs (prescription drugs and biologics other than vaccines) from drug manufacturers. Beginning January 2018, the OPPS generally pays 340B hospitals ASP minus 22.5 percent for separately payable Part B drugs that do not have pass-through status (while drugs with pass-through status are paid ASP + 6 percent). However, a district court ruling issued December 28, 2018, questions the Secretary's authority to pay ASP minus 22.5 percent, and thus CMS may change this payment rate in the future (American Hospital Association et al. v. Alex Azar II 2018).

9 Exparel, a non-opioid drug used to manage postsurgical pain, had pass-through status from 2012 through 2014 and was paid separately in both the OPPS and ambulatory surgical center (ASC) payment systems. Beginning in 2015, Exparel was packaged as a supply in both payment systems. In their analysis of Exparel use from 2013 to 2017, CMS found that the drug's use differed in the HOPD and ASC settings. First, even when the drug was paid separately, use of Exparel in ASCs was much lower than in HOPDs. In addition, in the HOPD setting, the use of Exparel continued to increase even after the drug began to be packaged. By contrast, in the ASC setting, the use of Exparel increased rapidly when it was paid separately as a pass-through drug from 2013 through 2014 but declined substantially when the drug was packaged from 2015 through 2017. In 2019, CMS unpackaged and began paying separately for Exparel when used in ambulatory surgical centers. The drug remains a packaged supply in the hospital outpatient setting.

10 Some devices, such as neurostimulators and infusion pumps for delivering drugs, are used primarily to treat chronic pain and are paid for separately by Medicare; they have been included as pass-through payments.

11 Buprenorphine extended-release injections, which are used to treat opioid addiction, were granted pass-through status effective July 1, 2018 (Centers for Medicare & Medicaid Services 2018c).

12 Examples of other low-cost drugs used in the hospital outpatient department that are bundled into the payment for primary services under the OPPS include anesthesia drugs; drugs that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals,

contrast agents, and stress agents); and drugs that function as supplies when used in a surgical procedure.

13 For each selected opioid and non-opioid drug commonly used in the inpatient and outpatient hospital settings, we matched all national drug codes (NDCs) to WAC unit list prices, where available, that were standardized in terms of a single unit (e.g., 1 mg/ml, 1 mcg, 1 percent). Drugs with only one NDC or where list prices are otherwise not available are indicated as "N/A." Drugs with AWP but not WAC price available are indicated by an asterisk. If the normal dosage of the drug included a range (e.g., 200–300 mg), these unit prices for WAC and AWP were then standardized in terms of the midpoint of a drug's normal dosage. If the normal dosage included a reference to kilograms (e.g., 1 ug/kg/min), a standard patient weight of 71.4 kg was used to determine the total normal dosage. NDCs with percentage units of measure (UOMs) were converted by checking the package-size UOM in Medi-Span. If a package had grams or milliliters as the UOM, the drug ingredient strength was multiplied by 10 and the NDC's UOM was changed to match the package-size UOM. If there were multiple UOMs associated with a combination, WAC is reported in terms of a single unit because of concerns about unit conversion to the normal dose. WAC is reported in terms of a single unit for the ropivacaine HCl injection solution and ropivacaine HCl epidural solution combinations because of concerns about the normal dose of UOMs.

14 In January 2018, all formulations of buprenorphine, including those for pain treatment, were removed from PDE analyses of potential opioid outliers. CMS stressed in communications with Part D plan sponsors that their overutilization policies should not interfere with enrollees' access to medication-assisted treatment, including buprenorphine products (Centers for Medicare & Medicaid Services 2018a, Centers for Medicare & Medicaid Services 2018g).

15 "These products contain acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4,000 milligrams per day, and often involve more than one acetaminophen-containing product" (Food and Drug Administration 2011).

16 A *drug potentiator* is defined as a chemical, herb, or other drug that is used to increase the effects of a substance, consequently increasing both the substance's and the potentiator's abuse potential.

17 Note that the OMS identifies potential outlier drug utilization issues at the beneficiary level and is not related to the current patient safety outlier reporting process, which tracks contract-level outliers for patient safety measures. The OMS uses a separate process for reporting and collecting responses to beneficiaries identified with potential drug utilization issues.

18 The Patient Safety Analysis website is a nonpublic platform operated by a CMS contractor, accessible only to authorized participants. Each plan sponsor accesses a secure space on the site that is separate from all other plan sponsors' spaces.

19 The Pharmacy Quality Alliance (PQA) is a multi-stakeholder membership organization that was established in 2006 as a public–private partnership with CMS shortly after the implementation of the Medicare Part D prescription drug benefit. PQA's quality measures are developed using a transparent, consensus-based process.

20 *Concurrent use* is defined as an overlapping supply for an opioid and a benzodiazepine for 30 or more cumulative days.

21 Recommendation 6 of the *CDC Guideline for Prescribing Opioids for Chronic Pain* states that opioids prescribed for acute pain should be limited to three days or fewer and that a supply for more than seven days is rarely necessary (Dowell et al. 2016).

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