AHLA

Journal of Health & Life Sciences Law

VOLUME 13, NUMBER 2 | OCTOBER 2019

FEATURED ARTICLES

NOTES & COMMENTS

BRIEF INSIGHT

OFFICIAL JOURNAL OF AMERICAN HEALTH LAWYERS ASSOCIATION

The mission of the AHLA *Journal of Health & Life Sciences Law* is to publish in-depth, professionally reviewed articles that are interesting and useful to intermediate and advanced health lawyers throughout the United States.

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is provided with the understanding that the publisher and authors are not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.—*From a declaration of the American Bar Association*

Consistent with the American Health Lawyers Association's educational mission, it is an objective of the AHLA *Journal of Health & Life Sciences Law* to be a forum for the free expression and interchange of ideas. Contributors to the *Journal* are not agents of the American Health Lawyers Association. The opinions and positions stated in the *Journal* are those of the authors and not of the American Health Lawyers Association, its staff, volunteers, editors, or editorial board.

The AHLA *Journal of Health & Life Sciences Law* (ISBN 978-1-4224-4585-3. ISSN 1942-4736) is published three times per year by the American Health Lawyers Association, 1620 Eye Street, NW, 6th Floor, Washington, D.C. 20006-4010. Telephone 202-833-1100. www.healthlawyers.org.

The reprint of American Health Lawyers Association publications (including the *Journal of Health & Life Sciences Law*) is handled by the American Health Lawyers Association. To request reprint permission (which will be addressed on a case-by-case basis), please contact Katherine Miller at kmiller@healthlawyers.org.

Subscriptions to the AHLA *Journal of Health & Life Sciences Law* are complimentary for members of the American Health Lawyers Association. Paid subscriptions are available at www.healthlawyers.org/journal.

AHLA Diversity+Inclusion Statement
In principle and in practice, the American Health Lawyers Association values and seeks to advance and promote diverse and inclusive participation within the Association regardless of gender, race, ethnicity, religion, age, sexual orientation, gender identity and expression, national origin, or disability. Guided by these values, the Association strongly encourages and embraces participation of diverse individuals as it leads health law to excellence through education, information, and dialogue.

From the Editor in Chief

Colleagues:

The weather is turning crisp in some parts of the country, the Presidential race is heating up in Iowa, and the October issue of the *Journal of Health & Life Sciences Law* has arrived!

Our two featured articles are on different business issues for physicians and hospitals:

- Medicare and Non-Covered Services: Beyond Opting Out addresses ways physicians, who have not opted out of Medicare, may nonetheless provide services to Medicare beneficiaries outside of the Medicare program.
- Whack-a-Mole to Pac-Man: The Evolving Influence of Hospital-Physician Alignment Agreements looks at how hospital-physician alignment models have evolved over the years and can even influence our response to health crises.

We also offer two Comments that discuss potential future developments in health care:

- CMS Attempts to Shift Risk and Cut Costs in Medicare Part D: How CMS's New Modernization Model Holds Up deconstructs Medicare's Part D contracting and whether the new model will accomplish policy goals.
- State Civil Commitment Laws: A White Paper is a presentation of the proceedings of an AHLA convener session that was held in conjunction with the Substance Abuse and Mental Health Services Administration. The convener addressed state laws regarding civil commitment and temporary hold laws, as well as the future of treating certain mental health populations.

Last, but certainly not least, is a Brief Insight on Risky Hospital Laboratory Billing Arrangements: A Sad Tale of Greed and its Consequences for Small Hospitals and Their Communities. The article details a laboratory billing arrangement entered into by some hospitals which ultimately led to suits by third-party payers, and in some cases, contributed to the hospitals' demise. This article is a cautionary tale for hospitals when analyzing unique revenue enhancing agreements.

As always, if you have thoughts about what the *Journal* should cover in future issues, are interested in writing for the *Journal*, or have other feedback, please email to Katherine Miller at kmiller@healthlawyers.org.

Since this is the last *Journal* communication for 2019, the Journal's Editorial Board and I wish you joy for the New Year!

Sincerely,

Susan O. Scheutzow

Susan O. Scheutzow
Editor in Chief, Journal of Health & Life Sciences Law

Featured Article

Medicare and Non-Covered Services: Beyond Opting Out

Daniel F. Shay

ABSTRACT: The practice of medicine, especially within the Medicare system, has grown steadily more complicated for physicians. In the past decade, various programs have threatened payments for failure to report certain data, while fraud and abuse laws and the False Claims Act place additional pressure on physicians to grapple with complex regulations. At the same time, physician compensation may not be increasing sufficiently to offset these and other administrative headwinds. As a result, physicians may find themselves drawn to alternate revenue streams offered by non-covered services. This article examines the allure of non-covered services and what types of services they are, and looks at the legal and practical implications of several different approaches to providing such non-covered services.

Daniel F. Shay, *Medicare and Non-Covered Services: Beyond Opting Out*, J. Health & Life Sci. L., Oct. 2019, at 3.

Medicare and Non-Covered Services

ARTICLE CONTENTS

INTRODUCTION

The modern practice of medicine can be grueling. Physicians often find themselves working longer hours to complete an ever-increasing number of administrative tasks, beyond the care they provide to patients. In recent years, physicians have faced multiple new burdensome requirements just to maintain documentation within the Medicare system. From the Physician Quality Reporting System (PQRS) to the electronic prescribing program, to Meaningful Use, and now the Medicare Incentive Payment System, physicians who participate in Medicare find themselves having to navigate more and more regulations just to be paid. Likewise, they face a dizzying array of fraud and abuse laws, including the federal anti-kickback law, the Stark statute and its regulations, the False Claims Act, and others. Meanwhile, many feel as if Medicare reimbursement is not commensurate with the added stress of navigating a byzantine system of regulations. As a result, many physicians are now trying to find compensation from alternate sources, such as through providing services that are excluded from or otherwise not covered by Medicare. Similarly, physicians have taken to entering into relationships with patients to provide "concierge" care. This article explores the legal and practical issues that physicians face in attempting to provide non-covered care within the Medicare setting.

THE ATTRACTION OF NON-COVERED SERVICES

Many physicians are currently unhappy with a range of changes within the Medicare system. For example, changes in Medicare's reimbursement of evaluation and management (E/M) services have reduced reimbursement by collapsing payment for E/M codes from levels 2-5 into a single "blended rate."[1] Although they face increasing administrative burdens, physicians are not seeing corresponding increases in reim-

1 Joyce Frieden, *Doc Groups Unhappy with Medicare's Proposed Payment Changes,* MedPage Today (Aug. 29, 2018), https://www.medpagetoday.com/practicemanagement/reimbursement/74830. *See also* Darius Tahir & Rachel Roubein, *Trump's Overhaul of Medicare Payments Angers Doctors,* Politico (Sept. 20, 2018), https://www.politico.com/story/2018/09/20/cms-evaluation-and-management-plan-draws-angry-response-from-doctors-794702. However, these changes will not go into effect until January 1, 2021. Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program. Medicaid Promoting Interoperability Program; Quality Payment Program–Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions from the Medicare Shared Savings Program–Accountable Care Organizations–Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, 83 Fed. Reg. 59452 (Nov. 23, 2018).

bursement. For example, the Medicare Incentive Payment System (MIPS) requires that physicians invest resources in terms of both time and money (*e.g.*, to implement electronic health records technology to meet the "Advancing Care" portions of MIPS), although MIPS itself has thus far produced relatively little by way of financial benefits: "2019 payment adjustments for MIPS [based on 2017 reporting year] could have ranged from -4% to +22%, depending on two scaling factors . . . . Based on 2017 performance data, MIPS 2019 payment adjustments are less than 2%, even for top performers, as the program requires budget neutral payments."[2] Similarly, from 2016 to 2017, physician groups saw continued increases in costs alongside an inability to similarly increase revenues, leading to operating losses. In one year, operating losses increased from 10% to 17.5% per physician for all physicians regardless of practice setting, according to the American Medical Group Association's 2017 Medical Group Operations and Finance Survey.[3] Total losses during the two-year period increased from a median of $95,138 to $140,856.[4] Relatedly, although gross professional revenue increased from roughly $1.2 million to $1.3 million, net professional revenue decreased at a median from $682,735 to $681,332, indicating that practice expenses continue to rise but practice revenues are not keeping pace.[5]

Primary care practices have also begun to face pressure from the rise in popularity of urgent care centers and retail clinics. Between 2012 and 2016, office visits to primary care physicians fell by 18%.[6] Insurers have also begun to partner with large corporations, offering "minute-clinics" and urgent care facilities. For example, CVS Health and Aetna have merged, meaning that Aetna's customer base will now have access to some 1,100 minute clinics operated by CVS Health.[7] Walmart and Humana have been in

2 Drew Voytal & Mollie Gelburd, MGMA, *Medicare Reimbursement Falls Short of Care Delivery Costs*, https://www.mgma.com/data/data-stories/2019-medicare-reimbursement-rates (last visited Sept. 15, 2019).

3 Press Release, AMGA, AMGA 2017 Medical Group Operations and Finance Survey Indicates that Healthcare Organizations Face Increased Cost Pressures amid Revenue Growth Challenges (Jan. 8, 2018), http://www.amga.org/wcm/AboutAMGA/News/2018/20180108.aspx. These findings are explained in greater detail in a transcript from an interview provided by the president of AMGA Consulting, posted February 14, 2017 at *Results of the AMGA 2017 Medical Group Operations and Finance Survey*, Besler (Feb. 14, 2018), https://www.besler.com/amga-2017-medical-group-operations-and-finance-survey-podcast/. *See also* Joanne Finnegan, *Costs Up, Revenues Down for Medical Groups, Survey Finds,* FierceHealthcare (Jan. 9, 2018), https://www.fiercehealthcare.com/practices/for-doctors-costs-go-up-revenues-go-down-amga-survey-fred-horton.

4 Press Release, AMGA. *See also* Joanne Finnegan, *Costs Up, Revenues Down for Medical Groups, Survey Finds,* FierceHealthcare (Jan. 9, 2018), https://www.fiercehealthcare.com/practices/for-doctors-costs-go-up-revenues-go-down-amga-survey-fred-horton.

5 Press Release, AMGA.

6 Reed Abelson & Julie Creswell, *The Disappearing Doctor: How Mega-Mergers are Changing the Business of Medical Care*, N.Y. Times (Apr. 7, 2018), https://www.nytimes.com/2018/04/07/health/health-care-mergers-doctors.html.

7 *Id.*

similar talks.[8] UnitedHealth Group likewise operates a large urgent care group, MedExpress, which has likely contributed to the ongoing competition between insurers to offer such services.[9]

As discussed more fully below, physicians who participate in Medicare must accept Medicare's payment under the Medicare Physician Fee Schedule (MPFS) for services covered under Medicare. Non-participating physicians are limited to 115% of the MPFS rate for the same services.[10] Physicians who have opted out of Medicare may charge whatever amount they please, but they must navigate the opt-out process and ensure they maintain their opted-out status. In other words, Medicare requires additional administrative work from non-participating providers and places strict limitations on the prices that such physicians wish to charge their Medicare patients, and for those physicians who opt-out completely, the physicians may charge what they like, but they too have significant administrative burdens.

These shifts within the industry, coupled with Medicare's payment restrictions, place pressure on primary care providers to generate additional revenue to cover the lost procedures and visits they would otherwise be performing for patients who also frequent these retail clinics. These pressures, in turn, drive physicians to look for additional sources of revenue for their practices. One option available to physicians who do not want to opt-out of the Medicare system entirely, but desire to expand their practices by offering services outside of the Medicare program and charge whatever they like, is for the physicians to offer services that are not covered under Medicare.

Defining Non-Covered Services

The actual range of services not covered under Medicare is broad, and it depends on how one considers the concept of coverage itself. Generally speaking, however, these services fall into four categories: (1) medically unnecessary services; (2) statutorily excluded services; (3) "unbundled" services; and (4) administrative services.

Medically unnecessary services are simply those services that are not covered because they have been deemed unnecessary by Medicare. Examples include elective surgeries or procedures, evaluation and management visits that take longer than is deemed medically necessary, insufficiently documented services, services that are otherwise limited in frequency but which the patient has requested in spite of such

8 *Id.*
9 *Id.*
10 Social Security Act § 1848(g)(2)(C), 42 U.S.C. § 1395w-4 (2019).

limits, or services where the diagnosis is not an appropriate basis for the delivery of the service itself. Medical necessity under Medicare can usually be determined by examining guidance published by the Centers for Medicare and Medicaid Services (CMS) in the form of National Coverage Determinations (NCDs); Local Coverage Determinations (LCDs), which are published by Medicare Administrative Contractors (MACs); and articles published by MACs that expand upon or clarify points within LCDs. Medicare also offers an online, nationwide, searchable coverage database through which LCDs and articles can both be found.[11]

Statutorily excluded services are those that have been specifically excluded from coverage in accordance with the enabling statutes for Medicare. These services include dental services; most foot care services; hearing aids; custodial care; personal comfort items; routine physical checkups; certain preventive examinations; immunizations other than influenza, pneumonia, or Hepatitis-B; cosmetic procedures; services performed outside of the United States or one of its territories; eyeglasses and eye examinations; most orthopedic shoes; services by immediate relatives; and assisted suicides.[12] Medicare has no obligation to pay for each of these services.

"Unbundled" services are services that must be billed together, or which are paid for as a discrete episode of care. These services cannot be billed separately; if they are, they will not be reimbursed. For example, certain services provided during the "global surgical period" cannot be "unbundled" from the surgery itself. Unbundling applies the concept of non-coverage to specific "circumstances" rather than to specific services. A service might be covered under different circumstances, but because it is being rendered in conjunction with other services and "bundled" together, the service at issue cannot be separately billed. For payment purposes, a single payment will be made for each of the bundled services.

Administrative services that are essential to the practice of medicine involve a range of activities for which Medicare makes no independent payment. For example, telephone calls and emails to patients to discuss treatment are not generally covered. Time spent recording notes, either on paper or in an electronic health record, is likewise not paid for separately by Medicare. Instead, Medicare generally considers these activities to be already included in its payment for services and therefore not independently reimbursed. Therefore, to bill such services separately would be considered improper unbundling.

---

11 *Medicare Coverage Database–Overview*, CMS, https://www.cms.gov/medicare-coverage-database/ (last visited Sept. 15, 2019). The "Advanced Search" is especially helpful in determining coverage requirements and pinpointing specific rules for services.

12 For the full list, *see* 42 U.S.C. § 1395y (2019).

PROVIDING AND BILLING FOR NON-COVERED SERVICES

Several options are available for providers who wish to bill for services that are not covered under Medicare. However, as a preliminary matter, the ability to bill patients directly for services depends on the physician's participation status under Medicare. This status breaks down into three categories: (1) participating, (2) non-participating, and (3) opted out. Participating physicians are those who have agreed to accept assignment, and they have executed a Medicare Participation Agreement.[13] Participating physicians are required to bill Medicare beneficiaries only for applicable copays and deductibles. In other words, a participating physician cannot accept any money from a Medicare beneficiary for a covered service other than a copay or deductible.

Non-participating physicians are those who have not elected to accept assignment. These physicians are limited in the amount that they can bill by what is known as the "Medicare limiting charge," itself a total payment of 115% of the MPFS rate for any given covered service. Non-participating physicians are not permitted to exceed this amount.

As discussed in greater detail below, physicians who have opted out are those who have elected to enter into contracts with Medicare beneficiaries, under which they may charge the beneficiaries at whatever rate they like (although neither the physician nor the beneficiary may submit the claim to Medicare for payment).[14]

A physician's participation status within Medicare requires careful consideration, both from the physician's perspective and from that of the physician's patients. If the physician is participating in Medicare, the physician may charge no more than the Medicare fee schedule amount, and must submit the claim to Medicare on behalf of the patient. If the physician is non-participating, the physician may choose whether to submit a claim to Medicare on the patient's behalf, or charge the patient for the service, but may only charge up to 115% of the Medicare fee schedule rate for the service. When the physician has opted out, the physician may charge the patient any amount the physician wants, but the opt-out applies to all Medicare services; a physician may not choose to opt out for some services and bill Medicare for others. Moreover, any patient who sees the opted-out physician must enter into a private contract with that physician whereby they agree not to submit claims to Medicare for the physician's services (as opposed to when the physician is non-participating, when the patient may

13 Form CMS-460, https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms460.pdf.

14 They must also have submitted an affidavit to Medicare stating that they have opted out. *See* CMS, Medicare Benefit Policy Manual Ch. 15, §§ 40.7–.9 (Rev. 259, July 12, 2019), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

choose to submit the claim to Medicare themselves). Both non-participating status and opting out may place additional burdens on the physician's patients, as the patients may have to submit their own claims to Medicare (in the case of a non-participating physician), or where the patients must sign an additional legal document and take on the expense of having to pay out of pocket for services otherwise covered by Medicare (in the case of an opted-out physician).

Medicare Billing Requirements and Non-Covered Services

Medicare's rules governing the provision of non-covered care vary based on circumstances. Simply stating that a service is not covered under Medicare does not end the inquiry. There is a difference under Medicare's rules between providing "medically unnecessary" services and services that are statutorily excluded.

A service that is "medically unnecessary" or which fails to meet coverage requirements might be covered under other circumstances. When the service in question falls into this realm, use of an Advance Beneficiary Notice (ABN) may be required.[15] An ABN is a document with which a physician notifies a patient of the fact that Medicare will not pay for the service being provided, and which informs the patient of their financial liability for the specific service being provided. Delivery of an ABN is mandatory: (1) when a physician believes that the care in question is not medically necessary; (2) for custodial care; (3) for hospice patients who are not terminally ill; (4) where home health service requirements have not been met; or, (5) where the patient's outpatient therapy cap has been exceeded.[16] An ABN must also be provided to a patient when the patient is receiving a Medicare preventive service that would have been covered, but where provision of the service exceeds guidelines regarding the frequency of such preventive services.[17]

By contrast, delivery of an ABN is optional: (1) when the service is statutorily excluded or (2) for services that fail to meet the definition of Medicare services.[18] Medicare's manuals describe delivery of an ABN under these circumstances as

15 *See* Form CMS-R-131, *available at FFS ABN*, CMS, https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html (last modified Aug. 1, 2019). The ABN form may only be provided to Medicare Part-A and Part-B patients; it is not appropriate to deliver to Medicare Advantage patients.

16 CMS, Medicare Claims Processing Manual Ch. 30 § 50.3.1 (Rev. 4197, Jan. 11, 2019; Rev. 4250, Mar. 8, 2019), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf.

17 *Id.* § 40.2.2(C).

18 As described in the Social Security Act § 1861, 42 U.S.C. § 1395x (2019).

"voluntary," and state that delivery "serves as a courtesy to the beneficiary in forewarning him/her of impending financial obligation."[19]

An ABN must be delivered prior to delivery of the service giving rise to the need for an ABN. The document must be signed by the beneficiary, with one copy retained by the provider providing the service, and one copy provided to the beneficiary. Forms for ABNs have been made available by CMS in both English and Spanish.[20] Providers should check CMS's website periodically to ensure that they are using the most up-to-date version of the form. At the time of this writing, the most recent form available was last updated in 2017 and is set to expire in March 2020. Providers are required to deliver the most current version of the form, and they must use the most appropriate version of the form based on the language the provider believes the patient is most able to understand.

If an ABN is properly delivered, the provider may bill the patient directly, and the patient will then be expected to pay out of pocket for the service. Thus, the ABN will permit the physician to directly bill patients or bill in excess of the Medicare fee schedule amount plus applicable copays and deductibles, although this only applies to non-covered services for which the ABN is delivered.

Concierge and Direct Primary Care Models

Two other approaches to providing non-covered care have become popular in recent years: so-called "concierge" medicine and Direct Primary Care (DPC). Each of these models focus on direct relationships between the physician and the patient, and they involve the patient paying the physician for services not otherwise covered under Medicare. However, there are some important distinctions between the two approaches.

Concierge Medicine

"Concierge" medicine derives its name at least partially from the level of availability and attentiveness the physician provides to the patient. The services provided are not covered under Medicare. As suggested by the model's name, the physician offers a higher-end experience for patients (and charges accordingly). The types of services offered can vary depending on the physician's specific model, but they often include:

19 Medicare Claims Processing Manual Ch. 30, § 50.3.2. As a practical matter, it is likely wiser for providers to deliver such an ABN to reduce the chances of having to re-explain to irate patients why they are being billed for the full cost of the service.

20 *See FFS ABN*, CMS, https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html (last modified Sept. 15 2019).

more immediate access to the physician (*e.g.*, 24/7 access to the physician's direct cell phone, rather than being required to use a service), the physician's assistance in coordinating the patient's specialist care (*e.g.*, making appointments on behalf of the patient, researching which doctor to use, etc.), executive physicals, extended visits, and luxury robes and shower facilities at the physician's office.

Because none of these services or items are covered under Medicare, the physician may continue to bill the patient's insurance for services that are otherwise covered, while charging the patient separately (and often expensively) for the additional services. Fees may be paid on an annual, semi-annual, or monthly basis, rather than a per-service fee. In this sense, the service and fee operate more along the lines of a "membership" rather than itemized charges for services.

The key to the workability of this approach is that none of the services offered are otherwise covered by Medicare, and most represent administrative services (*e.g.*, arranging for specialist care) or luxury items which are themselves not covered (*e.g.*, shower facilities and access to other spa-like amenities); they are not considered by Medicare to be included in the payment for what are otherwise covered services and go beyond what is considered part of the covered Medicare service.[21] Moreover, these services are rarely covered by private insurance, which means the model can be used across multiple different payers, as long as the physician follows payer rules regarding the provision of and billing for non-covered services. The model itself is attractive to physicians on multiple levels. Physicians are able to spend greater time with patients, meaning a lower volume of visits/services and smaller patient panels. Physicians also have time to perform administrative tasks, including drafting their visit notes, managing the ordering of laboratory tests and results, communicating with patients (on the phone, through patient portals, or otherwise), and generally easing the financial pressure on physicians to hurry through patient visits to maximize throughput. The model allows the physician to improve the value of the services they offer, rather than prioritizing volume.

Direct Primary Care

The DPC model functions similarly to concierge medicine, but offers fewer "luxury" services, and as a result is often less expensive. Under the DPC model, physicians opt out of Medicare, enter into contracts with patients to provide them with care directly,

21 The issue of whether services are, indeed, Medicare covered services can be complicated, however, as addressed in greater detail in the discussion on Legal Issues When Providing Non-Covered Services.

and the physician is paid for the services directly by the patient. The types of services offered under the DPC model typically include office visits, laboratory services, vaccinations, and the provision of generic drugs. In some cases, DPC practices offer electronic communication with patients and longer visits with patients. Patients, however, still retain insurance for hospitalization or specialist care.

Additional non-covered services offered under the DPC model (all of which could likewise be offered by a concierge model in addition to the "luxury" services offered under concierge care) include: (1) non-covered weight and stress management services (*e.g.*, such as consultations with a dietitian or lifestyle coach or even gym training); (2) completion of forms for schools, camps, or employers; (3) enhanced access services (*e.g.*, 24/7 cell phone access, same-day or next-day appointments, home visits, no waiting for scheduled appointments upon arrival at the office, etc.). Similarly, the DPC model may offer a range of communication options beyond simple cell phone access, such as video conferencing or texting, although patients might be limited to a fixed number of "electronic encounters" per month or be required to pay an additional fee upon exceeding the number of visits.[22]

The DPC model has the patient enter into a contract directly with the physician to receive a mixture of both covered and non-covered services. However, to provide the full range of services, the DPC model does require the physician to opt out of Medicare.

Opting Out of Medicare

Opting out of Medicare is a process by which a physician elects, similar to the DPC model, to enter into direct contracts with patients to provide services to the patients. When the physician has successfully opted out, he or she may charge the patient any amount for services rendered, even if the service is otherwise covered under Medicare. In effect, the physician steps out of the Medicare system almost entirely and engages in a one-on-one financial relationship with the patient. The process for opting out is time sensitive, requires careful attention to detail in managing the process, and requires the physician to enter into individual contracts with each Medicare beneficiary the physician treats prior to rendering services. However, given that the focus of this

22 Interestingly, these services might also fall within the range of non-covered Medicare services, depending upon the circumstances. Electronic encounters, such as telemedicine services, are limited with respect to coverage under Medicare. For example, telehealth visits are typically only available to rural beneficiaries or in other limited circumstances. Medicare Claims Processing Manual Ch. 12 § 190 (Rev. 4339, July 25, 2019), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf. If the patient is located outside of a rural area, then the visit will not be reimbursed because the telehealth service will be treated by Medicare as medically unnecessary.

article is on providing non-covered services, and the opt-out process is more focused around physicians providing covered services and billing for them at their own preferred rates, this article will not delve into any significant depth into opting out. [23]

LEGAL ISSUES WHEN PROVIDING NON-COVERED SERVICES

Billing patients directly for non-covered services naturally carries with it certain legal risks. Depending on the context in which physicians attempt to bill patients for such services, risks arise from several angles.

Medicare

Depending on the physician's participation status (whether participating, non-participating, or opted out), different penalties may apply for billing a Medicare beneficiary directly. If the physician has opted out of Medicare, then he or she may bill the patient directly without limitation. However, a participating physician who bills a patient directly could face exclusion for up to five (5) years and be subject to a civil money penalty of up to $2,000.[24] Non-participating physicians who bill Medicare beneficiaries directly may similarly face exclusion and/or the imposition of civil money penalties.[25]

Accordingly, any physician who is either participating or non-participating should take care to ensure that he or she is only billing patients directly for non-covered services. While this might seem simple, it is further complicated by the fact that Medicare has, in recent years, expanded its coverage of certain screening services as well as the provision of an annual wellness exam.[26] This, in turn, creates the risk that a physician attempting to bill for non-covered services–whether through a concierge model, a DPC model, or simply by providing an ABN to the patient–might actually be billing the patient for a service that is now covered.

In addition to the risks under federal law, physicians who bill in excess of Medicare's MPFS rate for services may face additional penalties under state law. Several states prohibit the practice of balance billing, which is where the physician bills the patient for the difference between the MPFS rate and the physician's charge, while

23 For a more in-depth examination of the opt-out process and its requirements, *see* James F. Hennessy, *Opting-Out: Legal Implications Concerning Provider Medicare Withdrawal*, 11 J. Health & Life Sci. L. 70 (2018).
24 Social Security Act § 1848, 42 U.S.C. § 1395w-4 (2019); *id.* § 1842(p)(3), 42 U.S.C. § 1395u.
25 *Id.* § 1848; *id.* § 1842(j)(2).
26 *See Preventive Services*, CMS, https://www.medicare.gov/coverage/preventive-screening-services (last visited Sept. 15, 2019).

accepting payment from Medicare. Billing a patient directly for such services could constitute a violation of such balance billing prohibitions.

For example, under Pennsylvania's prohibition, the act of "balance billing" is defined as charging a Medicare beneficiary "an amount in excess of the reasonable charge for the service provided, as determined by the United States Secretary of Health and Human Services," and prohibits the practice.[27] An initial violation will result in the Pennsylvania Bureau of Professional and Occupational Affairs (1) publicly reprimanding the physician and (2) ordering the physician to repay the victim the amount of excess payments made to the physician, "plus interest on that amount at the maximum legal rate" from the date of payment until the date the physician repays such amount.[28] A second violation imposes the same penalty plus a fine of $2,000. The fine increases to $5,000 for a third violation, and to $1,000 more than the last fine imposed for fourth and subsequent violations.[29]

Similarly, New York state law prohibits billing Medicare beneficiaries in excess of certain amounts. Generally, New York law prohibits physicians' charges to Medicare beneficiaries from exceeding 115% of the reasonable charge for the service, as determined by the Secretary of Health and Human Services.[30] A first violation will result in a fine of not more than $1,000 or less than three times the amount collected or charged in excess. For each subsequent violation within five years of the date of the immediately preceding violation, a fine of $1,000 (or three times the amount charged or collected in excess) up to $5,000 applies. Physicians who violate the provision must also return the amount collected in excess to the beneficiary.[31]

Ohio flatly prohibits health care practitioners from balance billing to any Medicare beneficiary, and defines the term "balance billing" to mean "charging or collecting from a [M]edicare beneficiary an amount in excess of the [M]edicare reimbursement rate for [M]edicare-covered services or supplies . . . except when [M]edicare is the secondary insurer."[32] Upon determining a violation has occurred, Ohio's Department

27 35 Pa. Cons. Stat. §§ 449.32, .34 (2019).
28 *Id.* § 449.35(a).
29 *Id.* § 449.35(b). Interestingly, penalties imposed under this law explicitly may not be considered cause to withhold, suspend, or revoke a health care practitioner's license. *Id.* § 449.35(e).
30 N.Y. Pub. Health Law § 19(1)(a) (2019). The law includes additional limitations, depending on the percentage of statewide Medicare Part B claims billed at or below the reasonable charge, and does not apply to office or home visits billed using CPT Codes 90000-90170.
31 *Id.* § 19(4).
32 Ohio Rev. Code Ann. §§ 4769.02, 4769.01(B) (2019). The definition exempts collecting deductibles or coinsurances required by the Medicare program.

of Health may publicly reprimand the violator, impose a penalty of $500, and require the violator to repay the Medicare beneficiary the amount overcharged plus interest.[33] Subsequent violations may also include a penalty of $2,000 per subsequent violation, and corporate officers and general partners of corporations who knew or should have known of the violations may also be penalized (in addition to the physician who actually violated the prohibition).[34]

Physicians must ensure that, when billing a patient directly, the service itself is not actually a covered service. This requires physicians to have a detailed understanding of Medicare's coverage rules, and to know which services are excluded from coverage altogether. Even if providing non-covered services, the physician may need to provide the beneficiary with an ABN. The physician also must be careful to avoid the practice of providing "routine notices," which can include ABNs, and which Medicare prohibits.[35]

Concierge and DPC Models

Both concierge care and the DPC model pose separate legal risks for physicians. Even if the physician has managed to sidestep the Medicare system's requirements, concierge and DPC models must still navigate state laws, which can raise ethical considerations, as well as state insurance laws.

Many state licensure laws and regulations for physicians treat violating generally accepted ethical rules of the profession as grounds for discipline, up to and including loss of licensure. For example, Illinois' Medical Practice Act treats as grounds for revocation, suspension, placement on probation, reprimand, refusal to issue or renew, or to take other disciplinary or non-disciplinary action–including the imposition of fines up to $10,000 per violation–if the physician engages in dishonorable, unethical, or unprofessional conduct "of a character likely to deceive, defraud or harm the public."[36] California's medical licensure laws treat as unprofessional conduct "the commission of any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon."[37] Tennessee's medical licensure laws grant its medical board the power to deny, withhold, suspend, or permanently revoke a physician's license for (among other things) "[u]nprofessional,

33 *Id.* § 4769.03(C).
34 *Id.* § 4769.03(D), (F).
35 CMS, Medicare Claims Processing Manual Ch. 30 § 40.2.2 (Rev. 4197, Jan. 11, 2019 & Rev. 4250, Mar. 8, 2019).
36 225 Ill. Comp. Stat. § 60/22(A)(5) (2019).
37 Cal. Bus. & Prof. Code § 2234(e) (2019).

dishonorable or unethical conduct."[38] Kentucky law defines as "dishonorable, unethical, or unprofessional conduct" conduct that has the effect of "bringing the medical profession into disrepute, including but not limited to departure from, or failure to conform to the standards of acceptable and prevailing medical practice" within Kentucky, "or failure to conform to the principles of medical ethics of the American Medical Association or the code of ethics of the American Osteopathic Association."[39]

These laws potentially (or explicitly, in the case of Kentucky) implicate the American Medical Association's (AMA) ethical guidelines. The AMA's Code of Medical Ethics permits the use of "retainer practices," defining them as contracts where the physician provides special non-medical services and amenities with individual patients "who are willing and able to pay additional costs out of pocket for such services."[40] However, the AMA cautions members with respect to the structure of such arrangements, and instructs physicians to uphold their obligations of fidelity to patients and their responsibility to treat all patients courteously and with respect for their rights and dignity, and to provide the same quality of medical care without regard to such contractual arrangements for non-medical amenities and services.[41]

The guidelines specifically require physicians entering into such contracts to:

a. Ensure that the terms of the retainer contract is presented clearly to patients, including the implications for their health care insurance (if known), and to not imply that additional or better medical care will be rendered under the agreement.

b. Ensure that patient decisions to enter into such contracts are voluntary, and that patients feel free to decline to enter such an arrangement.

c. Assist in the transfer of care to another, ideally local, physician if the patient declines to enter into the retainer relationship. If transfer is not feasible, the physician should continue rendering care under the terms of the patient's current health insurance.

d. Base treatment recommendations for patients on scientific evidence, professional guidelines, professional judgment, and "prudent stewardship."

38 Tenn. Code Ann. § 63-6-214(b)(1) (2019).
39 Ky. Rev. Stat. § 311.597 (2019).
40 AMA, Code of Medical Ethics Opinion 11.2.5, https://www.ama-assn.org/delivering-care/ethics/retainer-practices (last visited Sept. 15, 2019).
41 *Id.*

e. Bill honestly and transparently for services, and clearly distinguish charges for special services or amenities provided under the retainer relationship from medical services which are reimbursed by the patient's health care insurance.

f. Promote access to health care and provide care to patients in need without regard for their ability to pay, in keeping with other ethics guidance.[42]

Most of these requirements seem straightforward, and one would expect that a physician would have no difficulty in complying with them. The risk remains, however: if the physician fails to comply with these requirements, they may face discipline under their state licensure boards, including potential fines or loss of licensure.

The DPC model, in particular, also could potentially implicate state insurance laws, although this will depend heavily on the definitions provided under state law. A DPC model based on a monthly fee could be seen by state insurance authorities as a form of capitation. The key factor in analyzing these laws is the degree of risk the physician undertakes (and, of course, how the state insurance commissioner interprets the issue). For example, if the physician charges a membership fee coupled with a per-service fee, the physician is not undertaking any risk. If, on the other hand, the physician charges a flat monthly fee for providing services, then it could be argued that the physician has undertaken the risk that the patient will utilize the service heavily, which could be seen as insurance.

In response to these concerns, some states have enacted legislation that specifically exempts the DPC model from the definition of insurance, so as to permit the practice. For example, Missouri has passed a law governing the use of "medical retainer agreements," which are explicitly stated to not be insurance, and specifically exempting physicians entering into such arrangements to obtain a license or certificate of authority to sell or offer a medical retainer agreement.[43] The law also includes specific requirements for medical retainer agreements, including that (1) they must be in writing and signed by the physician and the patient or their legal representatives, (2) permit either party to terminate upon written notice to the other party,[44] (3) describe the specific health care services included under the agreement, (4) specify the fee, and (5) "[p]rominently state in writing that the agreement is not health insurance."[45]

42 *Id.*

43 Mo. Rev. Stat. § 376.1800 (2019). The term "medical retainer agreement" is defined as a contract between a physician and an individual patient where the physician agrees to provide certain health care services under the agreement for an agreed upon fee and period of time.

44 Although the law does not specify a length of notice.

45 Mo. Rev. Stat. § 376.1800(4) (2019).

Similarly, Colorado exempts "direct primary care agreements" from its insurance laws.[46] It defines such an agreement as a written agreement that (1) is between a patient, a government entity, or a patient's employer and a direct primary health care provider; (2) discloses and describes to the patient and to the person paying the DPC fee the primary care services to be provided; (3) specifies the periodic fee required and any additional fees that may be charged; (4) may allow the periodic fee and additional fees to be paid by a third party; (5) allows either party to terminate the agreement in writing upon notice; and (6) discloses to all parties under the agreement that it is not health insurance and does not meet any individual health benefit plan mandate that may be required under federal law, and that the patient is not entitled to health insurance protections for consumers.[47] Interestingly, it also requires that the agreement prohibit the provider from submitting a fee-for-service claim to an insurer for the services covered under the agreement.[48] Of course, concierge models that also use a retainer payment would likely fall within the scope of such state laws.

CONCLUSION

The practice of medicine can be frustrating for physicians, especially those working in primary care. They face large patient pools and relatively low reimbursement, all while having to navigate a range of unpaid administrative tasks. They may therefore seek alternate revenue sources, such as the rendering of services not otherwise covered by Medicare, such as through concierge or DPC models, or simply opting out. Concierge medicine may allow the physician to remain a participating provider with insurers (including Medicare), but carries with it the risks of providing services which the payer may deem already covered. The DPC model, on the other hand, steps outside of the insurance relationship, but requires physicians to enter into contracts directly with their patients. This, in turn, may raise questions on whether the arrangement falls within the scope of state insurance laws. While some states have taken steps to permit such arrangements, not every state has, so physicians must be careful in how they structure their contracts and business models. In time, Medicare and private payers may try to find ways to diminish the administrative burdens on physicians, but until that time, the lure of providing non-covered services will likely remain. J

46 Colo. Rev. Stat. § 6-23-102 (2019).
47 *Id.* § 6-23-101(1).
48 *Id.* § 6-23-101(1)(e).

Author Profile

DANIEL F. SHAY is an attorney at Alice G. Gosfield and Associates, P.C. His practice is restricted to health law and health care regulation focusing primarily on physician representation, fraud and abuse compliance, Medicare Part B reimbursement, and HIPAA compliance in the physician context. He also has a keen interest in intellectual property issues, including copyright, trademark, data control, and confidentiality. He has also focused his attention on provider control of commerce in data, electronic health records license agreements, physician advertising, enrollment in Medicare, quality reporting and quality measurement, physician use of non-physician practitioners, and physician use of social media. He speaks publicly and has published on all of these topics. He also regularly speaks to resident physicians on what to expect in their employment contracts. Mr. Shay received his Bachelor of Science degree cum laude in 2000 from Vanderbilt University and his juris doctorate degree from Emory University School of Law in 2003. Mr. Shay is admitted to the Pennsylvania Bar, and is a member of the American Health Lawyers Association. Contact him via email at dshay@gosfield.com.

Featured Article

Whack-a-Mole to Pac-Man: The Evolving Influence of Hospital-Physician Alignment Agreements

Andrea M. Ferrari and Jamie McIntyre[1]

ABSTRACT: In 21st century health care, the nature and terms of contracts between health care providers reflect an evolving patchwork of laws, regulations, and medical practice rules. On the flip side, since provider contracts govern the specifics of who will be paid for what services and under what conditions, provider contracts are primary drivers of the nature and terms of interactions between and among providers and between providers and patients. The dual status of provider contracts as both the cause and effect of laws, rules, and policy means that such contracts may be an important conduit through which laws, regulations, and policy impact care delivery. It also means that provider contracts, and those who assist in their drafting and implementation, may significantly influence the type and scale of effect that evolving laws, regulations, practice rules, and policy have on care delivery. Through the lens of the opioid crisis, this article will explore how provider contracts that include pay-for-performance (P4P) principles (contracts referred to as "incentive-based provider alignment agreements") both reflect and influence health care culture and practices, and the evolving role they may play in shaping the impact of laws, regulations, practice rules, and local and national policies.

Andrea M. Ferrari & Jamie McIntyre, *Whack-a-Mole to Pac-Man: The Evolving Influence of Hospital-Physician Alignment Agreements*, J. Health & Life Sci. L., Oct. 2019, at 21.

1 The authors would like to thank Mara Rendina for her contributions to this article.

Hospital-Physician Alignment Agreements

ARTICLE CONTENTS

INTRODUCTION: WHACK-A-MOLE AND PAC-MAN AS HEALTH CARE METAPHORS

A popular amusement park game, Whack-a-Mole, and a video game that revolutionized the video gaming industry, Pac-Man,can be used as metaphors to characterize the way the health care industry has generally addressed problems in the delivery of health care services: in a reactionary manner ("Whack-a-Mole") versus with deliberate strategy (the "Pac-Man" approach).

Whack-a-Mole

Whack-a-Mole is a decades-old arcade game that involves use of a mallet to "whack" toy moles back into their holes. The moles emerge (and re-emerge) from their holes at seemingly random intervals and in quick succession. The "whacking" is necessarily reactionary and quick, and sometimes brute. The name of this classic arcade game has been used in popular culture to refer to a situation in which attempts to solve a problem are blunt, short-lived, and piecemeal or superficial, resulting in only temporary or minor improvement.[2]

Societal responses to compelling and complicated health care problems have at times been whack-a-mole. At times, government and industry have implemented laws, rules, policies, and practices in ways that are reactionary and blunt, and ultimately turn out to be temporary fixes that are accompanied by the emergence or re-emergence of collateral problems. One example of this, among many, is the historical response to concerns about whether and how to address, attend to, and, on a broader scale, develop and deploy standardized approaches to patient pain. The initial response of the health care industry, which may have contributed to a collateral problem that we now refer to as "the opioid crisis," is used in this article as a basis for broader discussion about evolutionary changes in health care norms and practices, and the role that incentive-based provider alignment agreements may have in such evolutionary changes.

Pac-Man

Pac-Man is another decades-old game in which "a player attempts to guide a voracious, blob-shaped character through a maze while eluding attacks from opposing images which it may in turn devour."[3] It is a game of strategy in which the player advances to

2 *Whack-A-Mole–Definition of Whack-A-Mole by Lexico*, Lexico, https://en.oxforddictionaries.com/definition/Whack-a-Mole (last visited Sept. 27, 2019).

3 *Pac-Man–Definition of Pac-Man by Lexico*, Lexico, https://en.oxforddictionaries.com/definition/Pac-Man (last visited Sept. 27, 2019).

increasingly difficult play levels each time a maze is cleared.[4] In this article, Pac-Man is a metaphor for successfully and incrementally eliminating or evading problems to clear mazes of obstacles. It is also a metaphor for industry-wide transformative change.

The authors will elaborate on the latter point:

Pac-Man was one of the first video games to have broad mainstream distribution. Its popularity spread across the globe and was unprecedented.[5] It was, and still is, widely regarded as the seed for the "video game generation"–a cohort of children, teenagers, and young adults with a new and, at the time, unique combination of strategic gaming skills and eye-hand coordination and, eventually, an appetite for similar products. It encouraged a generation of coders to focus on the development of similar products that used data from a player's prior performance to adjust patterns of images and advance game difficulty. It became a template for many other popular video games and electronic applications. Arguably, the legacy of Pac-Man was a transition from checkers to Nintendo and, eventually, to a world of apps, smart phones, and the artificial intelligence emerging today. The impact of Pac-Man can be likened to the impact of data-driven value-based payments in health care today: transformative of both culture and expectations.

TRACING THE OPIOID CRISIS: A POTENTIAL EXAMPLE OF THE WHACK-A-MOLE APPROACH TO A HEALTH CARE CRISIS

In the early 2000s, when concerns about patient pain were reaching a crescendo, there were various legislative and regulatory efforts to improve the way health care providers assess and address patient pain. These included House Bill 2260, Title VI, Sec. 103, which passed the United States House of Representatives in 2000 to establish the "Decade of Pain Control and Research,"[6] as well as various state-level efforts to encourage improved bedside management of pain, such as California's Assembly Bill 791, which required hospital facilities licensed in California to include pain as an item to be assessed at the time that vital signs are taken.[7]

4 For more information about the features of Pac-Man, *see Pac-Man–Wikipedia*, Wikipedia, https://en.wikipedia.org/wiki/Pac-ManPac-Man (last visited Sept. 27, 2019).

5 There are many articles and other writings on the global popularity and impact of the video game Pac-Man. For an example and summary, *see Pac-Man–Britannica.com*, Encyclopaedia Britannica, https://www.britannica.com/topic/Pac-Man-1688279/ (last visited Sept. 27, 2019).

6 Pain Relief Promotion Act of 2000, H.R. 2260, 106th Cong. (2000), https://www.congress.gov/bill/106th-congress/house-bill/2260.

7 AB 791, S. Comm. on Bus. & Professions (Cal. 1999), https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=199920000AB791.

In 2001, the Joint Commission (then known as the Joint Commission on Accreditation of Healthcare Organizations or JCAHO), which was, and is, the premier accrediting organization for hospitals, introduced new pain assessment standards for accredited hospital facilities.[8] Using a term coined in a publication of the United States Veteran's Administration, hospitals dubbed pain the "fifth vital sign"[9] and adopted policies to ensure that patient-reported pain levels would be assessed and monitored throughout a patient's hospital stay, just as pulse, temperature, and blood pressure were assessed and monitored. [10] The theory, presumably, was that "what gets measured gets managed."[11]

At roughly the same time as when the health care industry was whacking the pain mole, other concerns about patient experience–about "patient satisfaction" in particular–emerged. Since some studies and literature suggested that patients with high pain ratings reported low satisfaction, some providers turned to the mallet of opioids to address the patient satisfaction mole.[12] Evidence-based literature at that time indicated that opioid-based pain control was generally safe and effective, and medical practice guidelines encouraged it.[13]

As control of patient pain and overall patient satisfaction improved, other issues emerged. For example, there were increases in unexpected fatal inpatient respiratory depression events related to opioid use.[14] There were increases in inpatient length of stay (LOS) and related costs to address ileus and other effects of inpatient intravenous opioid use.[15] Data suggesting an increasing incidence of opioid use disorders in

8 Donald M. Phillips, *JCAHO Pain Management Standards Are Unveiled*, 284 JAMA 428 (2000); *see* JCAHO pain management standards PC.01.02.07, PC.01.02.01 RI.01.01.01.

9 Dep't of Veterans Affairs, Pain: The Fifth Vital Sign (2000), http://www.va.gov/PAINMANAGEMENT/docs/Pain_As_the_5th_Vital_Sign_Toolkit.pdf.

10 For a helpful history and analysis of the 2000 JCAHO pain standards *see* David W. Baker, Exec. Vice President, Div. of Healthcare Quality Evaluation, The Joint Comm'n, The Joint Commission's Pain Standards: Origins and Evolution (2017), https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf.

11 This quotation is widely credited to management consultant Peter Drucker in the 1970s, although some writings suggest it originated with others long before then.

12 *Are Patient Satisfaction Surveys Fueling America's Opioid Epidemic?*, CBS News, Apr. 1, 2017, https://www.cbsnews.com/news/opioid-epidemic-doctors-say-hospital-patient-satisfaction-survey-fuel-dependence/

13 *See, e.g.*, Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 New Eng. J. Med. (1980), https://www.nejm.org/doi/10.1056/NEJM198001103020221.

14 *More on Avoiding Opiate Toxicity with PCA by Proxy*, Inst. for Safe Medication Practices, May 29, 2002, https://www.ismp.org/resources/more-avoiding-opiate-toxicity-pca-proxy.

15 Hector Vila et al., *The Efficacy and Safety of Pain Management Before and After Implementation of Hospital-Wide Pain Management Standards: Is Patient Safety Compromised by Treatment Based Solely on Numerical Pain Ratings?*, 101 Anesthesia & Analgesia 474 (2005), https://journals.lww.com/anesthesia-analgesia/fulltext/2005/08000/The_Efficacy_and_Safety_of_Pain_Management_Before.32.aspx.

post-operative patients grew.[16] Some data, perhaps largely unnoticed at the time, were pointing to the beginning of what we now refer to as the "opioid crisis." This is evidence of one of the almost inevitable realities of the whack-a-mole approach to solving problems–some moles will be missed as attention is placed on others.

THE ERA OF DATA-DRIVEN VALUE BASED PAYMENT: OPPORTUNITIES TO ADOPT A DIFFERENT APPROACH

In 2019, with the proliferation of value-based payment models and the more rapid and widespread availability and use of data and analytics to drive and refine behavior changes, pac-man may replace whack-a-mole as a means to address problems in health care. Health systems, the physicians who staff them, and certain other stakeholders in the health care delivery system are increasingly aligned in incentive-based provider alignment agreements that are driven by annual or more frequent data assessments and that impose shared risk on the parties for the response to such data. Arguably, these incentive-based provider alignment agreements offer potential for the health care industry to be more timely and effective in identifying and eliminating both the well-known and previously-unanticipated problems of care delivery. As mentioned earlier, the purpose of this article is to explore the nature of, and factors influencing, the current generation of data-driven incentive-based provider alignment agreements, and the influence that these contractual arrangements may have on the success of societal and health care industry efforts to respond to health care issues such as poor control of patient pain and the related opioid crisis.

Overview of Incentive-Based Provider Alignment Agreements in the Marketplace

With the ongoing market transition to value-based payment models, health care providers throughout the United States, including hospitals, health systems, physicians, and physician organizations, are subject to mounting pressure to improve quality, cost, and outcomes of their care delivery. The pressure arises from a variety of changes in health care financing and regulation, including, as just a few examples, hospital value-based purchasing,[17] bundled payments,[18] and introduction of the clinician

16 *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing Before the S. Caucus on Int'l Narcotics* (2014) (statement of Nora D. Volkow, Dir., Nat'l Inst. on Drug Abuse), https://archives.drugabuse.gov/testimonies/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

17 *The Hospital Value-Based Purchasing (VBP) Program*, CMS, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing.html (last modified Aug. 2, 2018).

18 *Bundled Payments for Care Improvement (BPCI) Initiative: General Information*, CMS, https://innovation.cms.gov/initiatives/bundled-payments/ (last updated Apr. 17, 2019).

Quality Payment Program (QPP) through enactment of the Medicare Access and CHIP Reauthorization Act (MACRA).[19] The pressure exists in an environment in which the decisions, orders, and actions of individual clinicians and managers–most notably, of *physicians*–drive the course and costs of patient care activity and yet, have historically been insulated from the consequences of their decisions, orders, and actions, even while the organizations they staff may be at substantial risk for the costs and outcomes.

With recognition of the historical misalignment of incentives between individual providers and managers and the organizations that they staff, there has been a proliferation of incentive-based provider alignment agreements that are aimed at aligning individual and organization stakeholders in pursuit of common care delivery goals through financial incentives. Critics of such arrangements point to various published studies which suggest that financial incentives paid to physicians have mixed results; that at best, they may be effective for changing short term behavior and processes, but not necessarily for changing patient outcomes over the long term.[20] This criticism perhaps overlooks the key influence of financial incentives. Even if their only impact is to raise awareness of desired process changes and facilitate the adoption of those changes for as long as the incentive is in effect, financial incentives still provide a valuable opportunity to effectuate desired changes, perhaps for a long enough period of time to determine whether the changes will truly influence outcomes. Not every desired or legally-mandated change will have the expected and desired effect on long term patient outcomes. This is one reason that practice guidelines and best practices, including those related to treatment of patient pain, have changed over time. One can never know the true impact of a change until one *makes* the change. Financial incentives, through incentive-based provider alignment agreements, are a means to effectuate change, even if not necessarily to guarantee a specific outcome from the change.

Perhaps the most well-known type of incentive-based provider alignment agreement is the service line co-management agreement, under which a provider organization (usually a hospital) and a physician entity, which may be a physician group practice or a joint venture entity formed between a hospital and/or various independent physicians or physician entities, enter into an agreement to jointly provide management services for the administration of a specific patient service line. The compensation for the manager is partially fixed in a "base fee" that is paid to the manager so long as specific tasks are performed, and is also partially in "at risk" in the form of incentives paid to the manager only upon achievement of specific measures of change in process or outcomes.

19 Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114–10, 129 Stat. 87 (2015).

20 M. Ruth Lavergne, *Financial Incentives for Physicians to Improve Health Care*, 189 Canadian Med. Ass'n J. E1505 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5718888/pdf/189e1505.pdf.

Exhibit 1. Service Line Co-Management Direct Contract Model

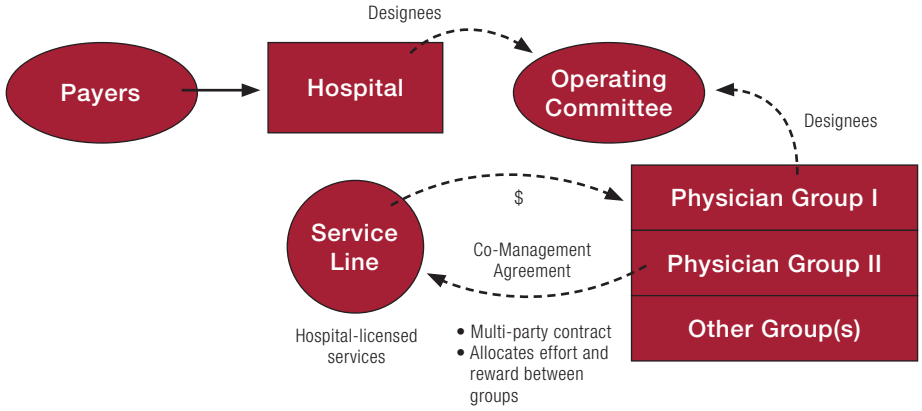
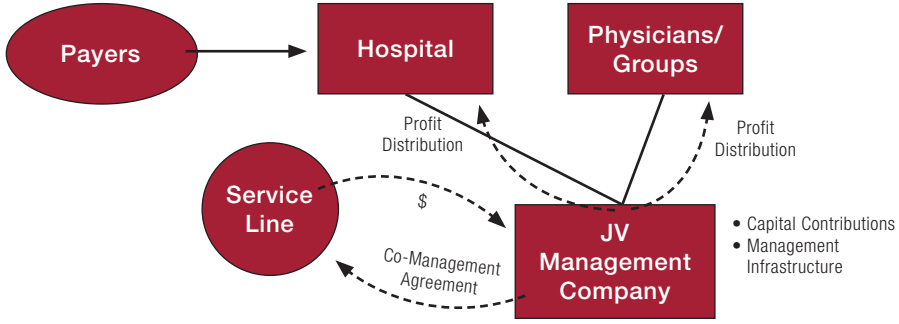


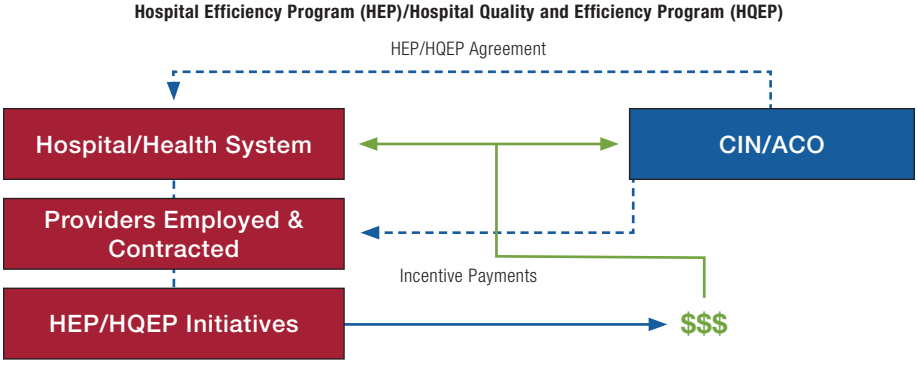
Exhibit 2. Service Line Co-Management Joint Venture Model



Although the service line co-management agreement may be the most well-known type of incentive-based provider alignment agreement, it is one of several that are common among hospitals and physicians. In recent years, "hospital efficiency programs" or "hospital quality and efficiency programs" (HEPs or HQEPs for short), which are based on a similar set of principles to service line co-management agreements but usually have a broader scope than a single service line, have gained popularity for their ability

to engage and align clinicians and managers across an entire organization (such as a whole hospital) or across a continuum of care (such as pre- to post-acute care).

Exhibit 3. Hospital / Health System HEP / HQEP Agreement



As federal lawmaking, commentary, and rulemaking have increasingly encouraged value-based provider incentives and seem to suggest a softening view of gainsharing,[21] the door has opened to more provider alignment agreements that are based on principles of gainsharing.[22] New gainsharing agreements are sometimes within the context of participation in a federal bundled payments program (such as the Bundled

21 Section 512(b) of MACRA required the Secretary of the U.S. Department of Health and Human Services, in consultation with the Inspector General of HHS, to submit to Congress "a report with options for amending existing fraud and abuse laws in, and regulations related to, titles XI and XVIII of the Social Security Act [], through exceptions, safe harbors or other narrowly tailored provisions, to permit gainsharing arrangements that otherwise would be subject to the civil money penalties described in paragraphs (1) and (2) of section 1128A(b) of such Act [], or similar arrangements between physicians and hospitals, and that improve care while reducing waste and increasing efficiency." That report was released late in 2015 and is available here: U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Report to Congress: Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements Between Physicians and Hospitals As Required by Sectsion 512(b) of the Medicare Access and CHIP Reauthorization Act of 2015, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Report-to-Congress-2015.pdf. Following the report, and effective January 6, 2017, OIG modified the gainsharing civil monetary penalties law to narrow the prohibition on payments to reduce services to Medicare beneficiaries to prohibit only payments to reduce "medically necessary" items or services (81 Fed. Reg. 88368, Dec. 16, 2016).

22 Rosemary Grandusky & Kathy Kronenberg, *Back to Basics: Hospital-Physician Gainsharing*, 59 Tr. Mag. (2006), https://www.jonesday.com/files/Publication/66fdb136-0fa7-4b89-8ff6-003f06b27574/Presentation/PublicationAttachment/476ab65d-2da8-469b-8ca0-047cf8aa6dbd/March%20Back%20to%20Basics.pdf.

Payments for Care Improvement (BPCI) Initiative)[23] or shared savings program (such as the Medicare Shared Savings Program (MSSP)),[24] and therefore subject to waiver of Medicare fraud and abuse laws.[25] Increasingly, however, they are not in this context, and for this reason (and given the complicated patchwork of laws and regulations these arrangements may implicate[26]), great thought and care is typically given to how they are structured and what behaviors they incentivize, as discussed below.[27]

Exhibit 4. Types of Gainsharing Agreements

Alignment Method	Defined	Primary Purpose/Focus	Initial Investment/ Financial Risk by Stakeholders	Longevity
Gainsharing	Sharing of cost savings from improved hospital or program efficiency	Hospital or program cost management, usually with simultaneous quality safeguards or improvements	Low to Moderate	Limited, unless new targets are identified
Service Line Management and Co-Management	Contractual or JV arrangement to enlist physicians to assist a hospital in cost and quality management of a specific service line	Hospital service line quality and efficiency	Moderate	Limited, unless new tasks and goals are identified
Clinically Integrated Network (CIN)	Collaborative venture directed at enhancing quality and value of health care for one or more specific populations/ clients	Population health management and cost and quality improvements for healthcare payors and providers	Usually High (Dependent on infrastructure in place to support tracking of services and outcomes)	Indefinite
Accountable Care Organization (ACO)	Collaborative venture (sometimes a CIN) for the express purpose of enhancing quality and value of care for an assigned population of Medicare beneficiaries	Population health management and cost and quality improvements for the Medicare program and its beneficiaries, with similar benefits for providers	Moderate to High (Dependent on infrastructure in place to support tracking of services and outcomes)	Indefinite (Minimum of 3 years of participation in the Medicare Shared Savings Program)
Accountable Care Entity (ACE)	Collaborative venture (sometimes a CIN) for the express purpose of enhancing quality and value of care for an assigned population of Medicaid or other patients	Population health management and cost and quality improvements for the subject health care coverage program	Moderate to High (Dependent on infrastructure in place to support tracking of services and outcomes)	Indefinite (If a Medicaid ACE, there may be a state-imposed minimum time for participation)
Combinations of Above	Alignment methods may co-exist, subject to certain safeguards against duplication of services and compensation	Transitional and/or multipurpose goals	Variable (Depends on combinations)	Longevity of each alignment method is generally the same as if each existed independently
Note: All terms used to refer to alignment methods are, to some degree, terms of art that may have varying meaning based on context and circumstances.				

23 *Bundled Payments for Care Improvement (BPCI) Initiative: General Information*, CMS, https://innovation.cms.gov/initiatives/bundled-payments/ (last updated Apr. 17, 2019).

24 As an example, see the Medicare Shared Savings Program (MSSP) final rule published Nov. 2, 2011 (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67802 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425)).

25 *Fraud and Abuse Waivers*, CMS, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html (last modified Dec. 31, 2018).

26 Office of Inspector Gen., Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (1999), https://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm.

27 U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Report to Congress: Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements Between Physicians and Hospitals As Required by Section 512(b) of the Medicare Access and CHIP Reauthorization Act of 2015, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Report-to-Congress-2015.pdf.

Finally, some long-common types of contractual arrangements, such as physician employment agreements, are acquiring new P4P features. As the QPP and other health care payer programs impose risk for patient costs and outcomes on the recipients of program health care payments, those recipients are looking to pass, or at least share, risk with their employees and contractors through compensation holdbacks or bonuses.

The common feature of all incentive-based provider alignment agreements is their element of at-risk compensation. This compensation is not tied to traditional measures of work such as time or relative value units but is instead based on achievement of performance measures that reflect the operational priorities of the payer of the compensation.

The inclusion of at-risk compensation is perhaps what makes incentive-based provider alignment agreements especially likely to mirror current laws, rules, and regulations. In the current regulatory environment, financial arrangements between providers–*especially* those that involve payments based on triggers other than traditional measures of "productivity," such as time or relative value units[28]–implicate various federal and state laws and rules. Depending on their specific details, incentive-based provider alignment agreements may implicate the Stark Law,[29] the federal Anti-Kickback Statute,[30] the federal Civil Monetary Penalties Law for gainsharing (the Gainsharing CMP),[31] and/or Section 501(c)(3) of the Internal Revenue Code if one of the parties to the agreement is a not-for-profit tax-exempt entity.[32] In many states, there are state corollaries to these federal laws[33]and/or other state laws and

28 Various publications from the Office of Inspector General (which enforces the federal Anti-Kickback Statute) and CMS (which enforces the Stark Law) indicate that remuneration should be fair market value for items or services actually provided. For an example, *see* Dep't of Health & Human Servs., Office of Inspector Gen., Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability (2015), https://www.oig.hhs.gov/compliance/alerts/guidance/Fraud_Alert_Physician_Compensation_06092015.pdf, stating "Physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide." Traditional measures of productivity, such as time spent or relative value units performed, have historically been the way the health care industry and those who enforce health care fraud and abuse laws have determined whether and how much services were actually performed.

29 42 U.S.C. § 1395nn (2019).

30 *Id.* § 1320a-7b(b).

31 *Id.* §1320a-7a(b).

32 I.R.C. § 501(c)(3) (2019).

33 Most states have physician self-referral prohibitions similar to the Stark Law and anti-kickback laws similar to the federal Ant-Kickback Statute. Most of these laws are distinguished from the federal laws by their application to non-Medicare and other non-federal health care program business and/or to a broader scope of services than the federal laws.

medical practice rules that must be considered, such as state fee-splitting prohibitions[34] or state law restrictions on specific types or forms of agreements or payments.[35]

Although circumstances and legal concerns vary, in general, the rules of thumb for financial incentives are the following: (1) the incentive arrangements are commercially reasonable in that they make business sense in both theory and practice;[36] (2) the incentives are fair market value (FMV) for the services or achievements they incentivize;[37] (3) payment of the incentives is not inappropriately tied to the volume or value of referrals of Designated Health Services (DHS)[38] or other business between the parties to the incentive agreement;[39] and (4) the incentives are based on actual documented achievements or services.[40] Individually and collectively, these rules of thumb encourage structuring and drafting incentive payment terms to substantially reflect the standards promulgated by health care regulatory bodies and accreditation agencies.

Payments based on standards promoted by regulatory bodies and accreditation agencies such as the Centers for Medicare and Medicaid Services (CMS), the Joint

34 An example of a state fee splitting prohibition is in Florida's patient brokering prohibition (Fla. Stat. § 817.505(1)(a) (2019)), which makes it unlawful to "[s]olicit or receive a commission, benefit, bonus, rebate, kickback, or bribe, directly or indirectly, in cash or in kind, or engage in any split-fee arrangement . . . ."

35 An example of a state law restriction affecting form of agreements or payments is California's anti-kickback statute (Cal. Bus. & Prof. Code § 650(b) (2019)), which prohibits payment of a percentage of gross revenue unless the payment is "commensurate with the value of the services furnished or with the fair rental value of any premises leased or provided by the recipient to the payer."

36 This definition of commercially reasonable is based on guidance provided by CMS in the preamble to the Stark II Phase II regulations and is consistent with guidance provided by the OIG. *See* Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16054, 16093 (Mar. 26, 2004) (to be codified at 42 C.F.R. pts. 411 & 424); *see also* OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4866 (Jan. 31, 2005).

37 There are a variety of reasons that incentives for physicians and other providers should reflect fair market value. If the incentives will be paid to a physician, the incentives may create a financial relationship under the Stark Law and it may be necessary for that financial relationship to meet an exception to the Stark Law, many of which explicitly require that the arrangement be consistent with or not exceed fair market value. To avoid scrutiny under the federal Anti-Kickback Statute, incentives should be fair market value to avoid an inference that may otherwise be made that the incentive is an inducement for referrals (United States v. Lipkis, 770 F.2d 1447, 1449 (9th Cir. 1985)).

38 Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001) (to be codified at 42 C.F.R. pts. 411 & 424), https://www.govinfo.gov/content/pkg/FR-2001-01-04/pdf/01-4.pdf.

39 Ensuring that payments do not vary with volume or value of referrals will help ensure against running afoul of (as applicable) the Stark Law, federal Anti-Kickback Statute, and/or state physician self-referral and/or anti-kickback laws.

40 *See, e.g.*, Dep't of Health & Human Servs., Office of Inspector Gen., Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability (2015), https://www.oig.hhs.gov/compliance/alerts/guidance/Fraud_Alert_Physician_Compensation_06092015.pdf, stating "Physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide."

Commission, or state licensing boards are generally assumed to be *prima facie* reasonable and less likely to be the subject of regulatory scrutiny. Moreover, since the priorities of the party that will pay the incentive compensation are likely to reflect that party's need to comply the rules and guidelines of applicable regulatory and accreditation bodies, it just makes sense that performance to the standards in those rules and guidelines would be the goal to which the paying party would want to align their contractors and employees. Finally, given the potential to leverage existing databases and infrastructure, tracking and documenting achievement to these standards may be far easier than discerning, tracking, and documenting other achievements for which data tracking and infrastructure has to be newly established. The "rub," however, is that care is needed to ensure that financial incentives through incentive-based provider alignment agreements are not inappropriately duplicative of other incentive payments that the recipient provider receives through other channels, such as other incentive agreements or payments directly from health plan payers. Duplicative payments may reduce the likelihood of meeting the standards of FMV and commercial reasonableness and complying with regulatory requirements.

WHACK-A-MOLE VERSUS PAC-MAN IN THE OPIOID CRISIS: THE REGULATORY BACKDROP OF THE OPIOID CRISIS

On March 29, 2017, shortly after President Trump's inauguration, the Office of the President issued an Executive Order establishing The President's Commission on Combating Addiction and the Opioid Crisis (the Commission).[41] The Commission's charge was to study ways to combat drug abuse, addiction, and the related crisis of opioid use and abuse in the United States.[42] In its final report, which was issued in December 2017, the Commission made 56 recommendations, including the following recommendations related to health care provider practices and standards:

1. Training related to safe provision of controlled substances to physicians and other prescribers upon renewal of DEA licensure;
2. Prescriber cross-referencing of data available through prescription drug monitoring programs (PDMPs); and
3. Discontinuation of physician evaluations that are based on patient self-reporting of pain scores.

41 Exec. Order No. 13784, 82 Fed. Reg. 16283 (Apr. 3, 2017), https://www.hsdl.org/?view&did=799917.

42 Chris Christie et al., The President's Commission on Combating Drug Addiction and the Opioid Crisis (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

Changes to CMS Rules and Medicare Conditions of Participation

Coincident with and following the development of the Commission's report, CMS, as the regulatory enforcement agency and standard-setter for providers and facilities that receive federal health care dollars through the Medicare and Medicaid programs, made several changes to its opioid-related guidance and mandates. These included:

- Issuing guidelines imposing limits on high dose opioid prescriptions by Medicare Part D prescribers.[43] The limits reflect evidence-based guidelines issued by the Centers for Disease Control and Prevention (CDC) in 2016.[44]
- Issuing the CMS Roadmap to Address the Opioid Epidemic (Roadmap),[45] which outlines CMS's three-pronged go-forward approach to combatting opioid misuse and abuse, to include:
  1. *Prevention* by identifying and stopping overprescribing patterns. This prong of the Roadmap includes incorporation of incentives for appropriate prescribing in star ratings for facilities and in the QPP for clinicians.
  2. *Treatment* through Medicare, Medicaid, and other health plan coverage for opioid use disorders; and
  3. *Data Collection and Analysis* to provide insight into use and effectiveness of opioid treatment. As part of this prong, CMS announced that it sent 24,000 letters to individual physicians to apprise them that their rate of opioid prescriptions was high in comparison to their peers, and it undertook an ongoing compilation and publication of regional data regarding high rates of opioid prescription under Medicare.

43 *A Prescriber's Guide to the New Medicare Part D Opioid Overutilization Policies for 2019,* MLN Matters, Nov. 1, 2018, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE18016.pdf.

44 Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain–United States, 2016*, Morbidity & Mortality Wkly. Rep. (MMWR), Mar. 18, 2016, https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.

45 CMS, CMS Roadmap: Fighting the Opioid Crisis (2019), https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf.

New Joint Commission Standards for Hospital Accreditation

The Joint Commission has faced significant pressure to revisit its standards for pain assessment and management.[46] In response, on January 1, 2018, it instituted updated standards.[47] The updated standards are in the Leadership (LD), Medical Staff (MS), Provision of Care, Treatment, and Services (PC), and Performance Improvement (PI) chapters of the Joint Commission's hospital accreditation manual. These updated standards require hospitals accredited by the Joint Commission to:

- Identify pain assessment and pain management, including safe opioid prescribing, as an organizational priority (LD.04.03.13);
- Actively involve the organized medical staff in leadership roles in organization performance improvement activities related to pain to improve quality of care, treatment, services, and patient safety (MS.05.01.01);
- Assess and manage the patient's pain and minimize the risks associated with treatment (PC.01.02.07);
- Collect data to monitor performance on pain assessment and pain management (PI.01.01.01); and
- Compile and analyze data on pain treatments (PI.02.01.01).

Specific requirements of the revised standards include, for example:[48]

- Identification of a medical staff leader or leadership team that is responsible for pain management and safe opioid prescribing and develops and monitors performance improvement activities (LD.04.03.13, EP1);
- Active involvement of the medical staff in pain assessment, pain management, and safe opioid prescribing through participation in the establishment of protocols and quality metrics, and reviewing performance improvement data (MD.05.01.01, EP18);

46 Susan Morse, *CMS, Joint Commission Pressed to Change Policies That Promote Opioid Pain Medicine Overuse*, Healthcare Fin., Apr. 14, 2016, https://www.healthcarefinancenews.com/news/cms-joint-commission-pressed-change-policies-promote-opioid-pain-medicine-overuse.

47 *Pain Management Standards for Accredited Organizations*, The Joint Commission, https://www.jointcommission.org/topics/pain_management_standards_hospital.aspx (last visited Sept. 28, 2019).

48 Charity Singleton Craig, *New Joint Commission Pain Standards Take Effect January 1, 2019,* CIPROMS Med. Billing, Dec. 6, 2018, http://www.ciproms.com/2018/12/new-joint-commission-pain-standards-take-effect-january-1-2019; *Approved New and Revised Pain Assessment and Management Standards*, 38 The Joint Commission Persp. 17 (2018), https://www.jointcommission.org/assets/1/18/APPROVED_New_and_Revised_Pain_Assessment_and_Management_Standards.pdf.

- Having defined criteria to screen, assess, and reassess pain that are consistent with the patient's age, condition, and ability to understand (PC.01.02.07, EP1);
- Reassessment and response to patients' pain through: (1) evaluation and documentation of response(s) to pain intervention(s); (2) progress toward pain management goals, including functional ability (for example, ability to take a deep breath, turn in bed, walk with improved pain control); (3) side effects of treatment; and (4) risk factors for adverse events caused by the treatment (PC.01.02.07, EP7);
- Collection of data on pain assessment and pain management, including types of interventions and effectiveness (PI.01.01.01, EP56); and
- Analyzing data regarding pain assessment and pain management to identify areas that need change to increase safety and quality for patients (PI.02.01.01, EP18).

Changes to State Laws and Rules Related to Opioid Prescribing and Handling

The National Conference of State Legislatures reports that as of October 31, 2018, 33 states had laws addressing prescribing and/or handling of opioids.[49] A significant number of these laws restrict initial opioid prescriptions to a 7-day supply, subject to certain enumerated exceptions such as cancer, traumatic injury, burn treatment and, in some limited cases, inpatient and/or post-operative settings.[50] However, some state laws explicitly allow or even require prescriber discretion in prescribing. As an example, Maryland law provides that prescribers must prescribe the lowest effective dose of an opioid for a time period that is not greater than what is needed for the expected duration of pain.[51] This restriction allows for, and indeed indirectly *requires*, consideration of circumstance-specific data, facts, and patient needs as a basis for clinical decision making.

Some state laws impose requirements or restrictions not only on the quantity but also the manner of opioid prescribing or handling. Michigan, for example, requires that prescribers discuss with patients the risk of opioid addiction.[52]

---

49 *Prescribing Policies: States Confront Opioid Overdose Epidemic*, Nat'l Conference of State Legislatures (June 30, 2019), http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx.

50 *Id.*

51 H.B. 1432, Reg. Sess. (Md. 2017).

52 Michigan Opioid Laws: Frequently Asked Questions (FAQs) (2019), https://www.michigan.gov/documents/lara/LARA_DHHS_Opioid_Laws_FAQ_05-02-2018_622175_7.pdf.

In general, state laws are in flux and continue to evolve as more is learned about opioids, their current and historical role in patient care, and the nature and magnitude of problems with addiction.[53] Variations in laws by state are due to a variety of factors, including changes or long-standing differences in locality-specific patient characteristics, the varying composition and rulemaking authority of state medical boards, and the sometimes changing state-by-state differences in general attitudes about health care provider regulation. As was noted in a white paper summarizing the results of the American Health Lawyer's Association's convener session on opioids, "the provider community is often unaware of how frequently provider standards may change in his or her state . . . what may be deemed "appropriate" prescribing one day could morph into "inappropriate" prescribing over time without a provider being aware of the shift."[54] As discussed below, one role and benefit of incentive-based provider alignment agreements is to raise *awareness* of changing standards, in addition to encouraging adoption of them.

THE ROLE OF INCENTIVE-BASED PROVIDER ALIGNMENT AGREEMENTS IN CHANGING BEHAVIOR: THE LESSONS OF OPIOID USE AND ABUSE

Broadly speaking, the at-risk compensation in incentive-based provider alignment agreements generally reflects measures in four distinct focus areas: (1) care quality; (2) cost control and cost avoidance; (3) improved or otherwise positive patient experience, including patient satisfaction; and (4) improved care delivery processes.[55] Within each of these four focus areas, there may be many different and annually varying metrics reflecting the specific needs and priorities of the time and circumstances. In and around the Decade of Pain Control and Research, metrics tied to each of these four focus areas may have included aspects that influenced the prescribing and use of opioids.

Care Quality Incentives

In both hospital service line co-management agreements and HQEPs, financial incentives in the quality category have historically reflected achievements meeting

53 *Prescribing Policies: States Confront Opioid Overdose Epidemic*, Nat'l Conference of State Legislatures (June 30, 2019), http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx.

54 AHLA, The Opioid Crisis: Understanding the Complexities, Acknowledging the Challenges, and Exploring Possible Solutions 10–11 (2019), https://www.healthlawyers.org/find-a-resource/HealthLawHub/Documents/Opioids/White%20Paper.pdf.

55 *What Is Pay for Performance in Healthcare?*, NEJM Catalyst (Mar. 1, 2018), https://catalyst.nejm.org/pay-for-performance-in-healthcare/.

the standards of the CMS hospital value-based purchasing program, which encompassed outpatient prospective payment system (OPPS) metrics relating to control of patient pain until 2017.[56] As discussed above, incentives to tailor care to these measures may have contributed to the widespread and liberal use of opioids in efforts to ensure proper pain control.

In addition to incentives based on CMS standards, incentives in the quality category have historically included incentives to reduce inpatient LOS, a legally controversial[57] but nonetheless relatively common target for financial incentives in alignment agreements between hospitals and physicians.[58] Incentives to reduce LOS may have increased physicians' propensity to more rapidly discontinue intravenous opioids and discharge patients with oral opioids. Higher prevalence of oral opioids in the home setting might have contributed to increased rates of dependency, diversion, and abuse.[59]

Cost Control and Avoidance Incentives

Cost control and cost avoidance are similar concepts but are usually considered to be subtly distinct. Cost control is generally defined to encompass actions that reduce current spending, while cost avoidance is usually defined to encompass actions that avoids costs in the future.[60] Historically, the cost avoidance category may have included financial incentives to encourage surgical avoidance and the pursuit of noninvasive alternatives to surgery, thereby limiting surgical interventions to a last resort. These incentives may have inadvertently encouraged more liberal and long term use of oral opioids for pain control during extended periods when medical or other noninvasive therapies were tried or had failed.[61] Both cost control and cost avoidance incentives

56 Press Release, CMS, CMS Finalizes Hospital Outpatient Prospective Payment System Changes to Better Support Hospitals and Physicians and Improve Patient Care (Nov. 1, 2016), https://www.cms.gov/newsroom/press-releases/cms-finalizes-hospital-outpatient-prospective-payment-system-changes-better-support-hospitals-and.

57 John Nelson, *Chapter 27. Designing a Hospitalist Compensation and Bonus Plan*, Access Med., https://accessmedicine.mhmedical.com/content.aspx?bookid=496&sectionid=41303985 (last visited Sept. 28, 2019).

58 James H. Reynolds & Daniel T. Roble, *Improving Clinical Quality and Sharing the Profits With Your Physicians*, 30 Physician Executive 12 (2004).

59 *Community and Outpatient Use and Abuse of Opioids*, Premier Safety Inst., http://www.premiersafetyinstitute.org/safety-topics-az/opioids/community/ (last visited Sept. 28, 2019); Carlos A. Pino & Melissa Covington, *Prescription of Opioids for Acute Pain in Opioid Naïve Patients*, UpToDate, https://www.uptodate.com/contents/prescription-of-opioids-for-acute-pain-in-opioid-naive-patients (last updated May 14, 2019).

60 Jennifer Dawson, *Cost Avoidance vs. Cost Savings*, G2 Blog (Aug. 31, 2018), https://www.g2intelligence.com/cost-avoidance-vs-cost-savings-whats-the-difference/.

61 MedPac, Report to Congress: Medicare Payment Policy, Mandated report: Opioids and alternatives in hospital settings–Payments, incentives, and Medicare data, Ch. 16, p. 451 (Mar. 2019), http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch16_sec.pdf?sfvrsn=0.

may have discouraged use of certain opioid-alternatives for pain control, including nerve block procedures, which, although they may be clinically effective, are surgical interventions that have historically been considered to be a more costly treatment option than oral pain medications.

Incentives for Improved Patient Experience and Satisfaction

In the past, measures in the patient experience or patient satisfaction category were likely to have tied some portion of at-risk compensation to scores on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)[62] and/or Press Gainey[63] surveys, either of which may have incentivized prescribing of opioids as a means to ensure patient satisfaction with pain control.[64]

Care Process Incentives

Measures in the care process category often focus on development and use of protocols and pathways to optimize outcomes in care delivery.[65] In the Decade of Pain Control and Research, and for some time after (*i.e.*, while pain remained the fifth vital sign), the focus of many of these protocols and pathways on pain assessment and control may have contributed to the advancement of a pain control culture in which opioids grew in popularity as a default therapy or treatment of first resort. As noted above, the prevailing practice guidelines of the time indicated that pain was something to be eradicated and that opioids were a safe and effective means for doing so.[66]

---

62 David Betts et al., Deloitte Ctr. for Health Sols., The Value of Patient Experience: Hospitals with Better Patient-Reported Experience Perform Better Financially (2016), https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-dchs-the-value-of-patient-experience.pdf.

63 *Id.*

64 Teresa A. Rummans et al., *How Good Intentions Contributed to Bad Outcomes: The Opioid Crisis*, 93 Mayo Clinic Proc. 344 (2018), https://www.mayoclinicproceedings.org/article/S0025-6196(17)30923-0/pdf; Sara Heath, *How Hospitals Can Raise Patient Satisfaction, CAHPS Scores*, Patient Engagement HIT, May 5, 2017, https://patientengagementhit.com/features/how-hospitals-can-raise-patient-satisfaction-cahps-scores.

65 Rachel M. Werner et al., *Does Hospital Performance on Process Measures Directly Measure High Quality Care or Is It a Marker of Unmeasured Care*, 43 Health Servs. Res. 1464 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2653884/pdf/hesr0043-1464.pdf.

66 Brian F. Mandell, *The Fifth Vital Sign: A Complex Story of Politics and Patient Care*, 83 Clev. Clinic J. Med. 400 (2016), https://mdedge-files-live.s3.us-east-2.amazonaws.com/files/s3fs-public/issues/articles/Mandell_June16_Blurb.pdf.

THE FUTURE: ADOPTING A "PAC-MAN" APPROACH TO ADDRESSING HEALTH CARE PROBLEMS AND USING INCENTIVE-BASED PROVIDER ALIGNMENT AGREEMENTS AS ONE OF THE TOOLS

Incentive-Based Provider Alignment Agreements can play an influential role in how the provider community responds to health care problems and crises, and the cornerstones of these agreements are money and data. This section will discuss examples of initiatives and incentives that can effectively engage the provider community to respond strategically to a crisis.

The Cornerstones: Money and Data

While the health care industry is certainly familiar with the phrase "what gets measured gets managed," the industry also has a firm grasp of the old concept that "money talks." The terms of contracts can determine what the money says when it talks, meaning what information, messaging, and priorities the money conveys. Provider financial incentives that reward review of and specified responses to data will speak to the importance of the data and of the specified response. In the process, they may cause more providers to review such data and engage in the desired response.

Not all providers will engage fully in incentivized activities, of course. Just as federal income tax incentives only somewhat influence purchasing decisions for fuel-efficient cars and energy-efficient windows,[67] provider financial incentives will only "somewhat" influence actual provider practices and decisions. However, even "somewhat" influence can be significant influence, and may be significant enough to cause cultural shift, as has arguably been the case of fuel-efficient cars and emergency-efficient windows.[68]

The magnitude of "somewhat" influence and the related magnitude of an associated cultural shift are likely to be functions of the extent to which financial incentives are of an appropriate dollar amount. *How much* money is allocated to those who do something says as much as, or even more than, whether money is allocated at all. This is one reason that the payment amounts tied to financial incentives are of critical importance. Financial incentives that are either too large or too small for their stated purpose are subject to regulatory scrutiny for potentially being not commercially reasonable, not FMV, inappropriately based on something other than a desire to

67 Arik Levinson, *Energy Efficiency Standards Are More Regressive Than Energy Taxes: Theory and Evidence*, 6 J. Ass'n Envtl. & Resource Economists S7 (2019), http://faculty.georgetown.edu/aml6/pdfs&zips/RegressiveMandates.pdf.

68 Molly F. Sherlock, Cong. Research Serv., The Value of Energy Tax Incentives for Different Types of Energy Resources (2019), https://fas.org/sgp/crs/misc/R44852.pdf.

change quality or cost behaviors (such as volume or value of business referrals), or otherwise not legitimate under applicable law. This is because they do not make sense as a means to obtain the targeted results. On the other hand, financial incentives that are of an appropriate amount and are implemented with appropriate data-based safeguards generally make sense as a means to effectuate desired behavior change.

Returning to the earlier discussion of the four general focus areas of incentive-based provider alignment agreements, the authors propose that these four categories of financial incentives create opportunities to address health care problems, like the opioid crisis, in a meaningful way that reflects and is responsive to changing culture, as well as to legal, regulatory, and medical practice rule requirements. Below is a general overview organized by focus area.

Care Quality Incentives

Care quality incentives may be tailored to reflect key provider practice recommendations of the Commission's report, as well as the new CMS, Joint Commission, and state law pain assessment and prescribing standards. Translating these recommendations and standards into incentive-driven performance targets may accomplish three things: (1) raise awareness of the new recommendations and standards; (2) increase the likelihood of provider compliance with the new recommendations and standards; and (3) facilitate more rapid data collection for purposes of evaluating successes, identifying deficiencies, and assessing overall outcomes of adoption of the recommendations and standards as needed to evaluate and evolve existing standards and lay the groundwork for establishing standards and recommendations for the future.

As an example and illustration, consider a provider alignment agreement with financial incentives targeting: (1) regular prescriber training for safe prescription and provision of controlled substances; (2) prescriber cross-referencing of data available through PDMPs at the time of prescribing; and (3) compliance with a state opioid prescribing law such as Maryland's.

In a service line co-management agreement or HQEP, attendance at annual, quarterly, or other periodic training may be a requirement and trigger for an incentive payment, either as a performance metric or as a gatekeeper for incentive payments earned through a different performance metric. In an HQEP or the distribution plan of an ACO or CIN, documented attendance at regular opioid prescribing training may be a "citizenship measure" that entitles providers to incentive payments independent of other performance measures. Whether in the form of a quality performance metric, gatekeeper, or citizenship measure, an incentive for regular attendance at training

(1) raises awareness of the need for training in the provider community; (2) increases the probability of providers actually attending training; and (3) provides an opportunity through the content of the training sessions to convey or provide access to the data that will be needed to successfully achieve other practice recommendations, including, for example, the recommendation for cross referencing PDPMs when prescribing opioids.

Although training sessions may convey information related to PDMPs and what data must be reported to them, a separate performance metric may be needed to target the frequency with which prescribers access PDMPs when prescribing. Audit trails and/or attestations may be used to determine whether and the extent to which this frequency metric is achieved, as well as to capture data that may be relevant to compliance with state practice rules and guidelines. Certain metric designs encourage review and documentation of available data to support treatment decisions. Metrics tailored to a state law such as Maryland's may be so tailored and may be both *driven by* and *sources of* process and outcomes data.

Cost Control and Cost Avoidance Incentives

Although opioids are not particularly expensive, the costs of opioid dependence and addiction are likely to be greater over the long term than costs of short term use of alternatives.[69] On this basis, cost avoidance metrics might be tailored to encourage development and consideration of opioid dependence mitigation strategies and opioid alternatives. Such metrics may augment, rather than supplant, metrics aimed at surgical avoidance. For example, physicians may be incentivized to prescribe opioids only as the last resort prior to surgical intervention, and only after considering and properly documenting the indications for and individual patient response to physical therapy, non-opioid pain relievers, and other opioid alternatives, including non-traditional approaches such as acupuncture or massage therapy.

Some arrangements may incorporate incentives to ensure that, when opioids are indicated, they are prescribed in accordance with internally adopted best practices or standards, with state practice rules and/or with state or CDC guidelines. These types of incentives serve three purposes: (1) raise awareness of the existence and details of applicable internal standards, state practice rules, and CDC and/or state guidelines, which are probably evolving and may be unknown to some practitioners; (2) encour-

69 Hilary Aroke et al., *Estimating the Direct Costs of Outpatient Opioid Prescriptions: A Retrospective Analysis of Data from the Rhode Island Prescription Drug Monitoring Program*, 24 J. Managed Care & Specialty Pharmacy 214, https://www.jmcp.org/doi/pdf/10.18553/jmcp.2018.24.3.214.

age compliance with the applicable rules and guidelines; and (3) reduce costs associated with inappropriate prescribing, including costs related to potential legal claims against the providers who are the parties to the particular incentive-based provider alignment agreement. A fourth and collateral purpose of these types of metrics is to, through the tracking of compliance with the metrics, create a data set addressing the availability and use of opioid alternatives and assess and track outcomes of those alternatives. Such data may be helpful for future creation and timely and appropriate adjustment of policies and guidelines to improve both quality and cost of care.

In the context of hospital service line co-management agreements and HQEPs, the creation of such a data set may assist a hospital to comply with the new Joint Commission standards requiring: (1) collection of data on pain assessment and pain management, including types of interventions and effectiveness (PI .01.01.01 EP56), and (2) analyses of data to identify areas that need change to increase safety and quality of patient services (PI.02.01.01 EP18).

In the context of an ACO or CIN distribution plan, or a practitioner employment or professional services agreement, creation of such a data set, and of practitioners' access to it, may assist with facilitating and advancing compliance with the CMS and QPP standards for identifying and stopping overprescribing patterns.[70]

Incentives for Improved Patient Experience and Satisfaction

In the patient satisfaction category, new metrics may be tailored to ensure that patients' pain and responses to treatments for pain are given the proper attention without necessarily prescribing opioids. Patient survey questions might focus on translation of the Joint Commission's new pain assessment standards to good practices for patient interactions, and may include, consistent with PC.01.02.07, EP7, questions pertaining to whether: (1) the patient was asked about their past response to pain interventions; (2) the patient was asked about side effects of treatment; (3) the provider adequately discussed with the patient the risk factors for adverse events that were associated with the treatment options; and (4) the patient is satisfied with the communication process.

70 Barry R. Meisenberg et al., *Assessment of Opioid Prescribing Practices Before and After Implementation of a Health System Intervention to Reduce Opioid Overprescribing*, 1 JAMA Network Open (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6324493/.

Data from the responses to these questions may be tracked with other data to meet the data goals of the CMS and Joint Commission standards and to help inform future policies, rules, and processes.

Care Process Incentives

Care process incentives may be tailored to foster provider engagement in the development and adherence to protocols and policies that will encourage compliance with CMS and/or Joint Commission standards, and/or with applicable state law rules and guidelines. In the context of service line co-management agreements and HQEPs, incentive payment criteria may focus on compliance with one or more of the following Joint Commission standards: (1) identification of a medical staff leader or leadership team that is responsible for pain management and safe opioid prescribing, and develops and monitors performance improvement activities (LD.04.03.13, EP1); (2) active involvement of the medical staff in pain assessment, pain management, and safe opioid prescribing through participation in the establishment of protocols and quality metrics, and reviewing performance improvement data (MD.05.01.01, EP18); and (3) having defined criteria to screen, assess, and reassess pain that are consistent with the patient's age, condition, and ability to understand (PC.01.02.07, EP1). Achievement of the payment criteria may be measured on a tiered basis, with achievement at the most minimal level (for example, a staff leader being identified by name and preliminary protocols drafted) earning a lesser incentive payment or merely being a condition for earning a base fee, and achievement at a higher level (for example, protocols are both adopted and implemented and there is proven success in improving care) earning a more substantial incentive payment.

Although the referenced Joint Commission standards apply to hospitals and are most directly applicable to hospital-physician alignment arrangements such as service line co-management agreements and HQEPs, they are based on thought-leader input for evidence-based clinical practice and may be a good foundation for behavior changes in organizations other than hospitals. They may be, for example, a reasonable basis for incentive payments made in the context of ACO/CIN participation agreements and funds distribution plans. Data regarding the correlation between success on these metrics and improved patient outcomes may be helpful for planning and adjusting future metrics and policy recommendations.

CONCLUSION

In the new age of data, incentive-based provider alignment agreements may play an unprecedented and particularly impactful role in translating laws, regulations, and medical practice rules and standards to changes in health care practices and behaviors, as well as in providing a pool of data to inform future laws, regulations, and practice rules and standards.

This means that incentive-based provider alignment agreements, depending on how they are structured and the magnitude and details of incentives offered, may significantly affect whether, how, and the extent to which the health care industry effectively addresses public health and health care delivery issues, including, in our example, patient pain and the opioid crisis.

Thoughtfully structured incentives, which generally means incentives of an appropriate amount to incentivize desired conduct in a legally compliant manner, along with provisions for rapidly but carefully measured results, can drive cultural change. In a world where "what gets measured gets managed" and "money talks," properly valued data-driven financial incentives may be powerful game changers. J

Author Profiles

ANDREA M. FERRARI is a Partner at HealthCare Appraisers in the company's corporate headquarters in Boca Raton FL. Previously, she was in the health law practice of a large international law firm, where she provided transactional and regulatory counsel to various types of health care clients. She has more than 22 years of experience in the health care industry, including serving as associate general counsel to a public health system, in-house in an academic medical center, and providing consulting and management for clinical trials, health care quality research, and related contracts. Her experience and focus areas include assisting in the transition to value-based payments, including structuring, evaluating and identifying issues in incentive payments in the context of CINs, ACOs, gainsharing arrangements and HQEPs; research and clinical trial agreements, including assisting clients with budgeting and planning provider compensation in the context of clinical and other research agreements; provider recruitment and retention arrangements, including income guarantees and recruitment bonuses; compensation issues for public, tax-supported and safety-net provider organizations, including public hospitals and health systems; and academic affiliations and compensation for academic and uniquely-experienced Thought-Leader and "Rockstar" physicians. Andrea received a Juris Doctor with concentration in health law and Master of Public Health from Boston University. Contact her via email at aferrari@hcfmv.com.

JAMIE McINTYRE is a Director at HealthCare Appraisers and works out of the company's corporate headquarters in Boca Raton FL. She previously worked as the contract administrator for a 425-bed tertiary care hospital in Jacksonville FL, where her duties included oversight of the lifecycle of hospital contracting, including physician and referral-source agreements, vendor agreements, tissue procurement, research and IRB agreements and school affiliations, as well as accounting responsibilities for seven hospital-affiliated entities. Prior to this, she served as a program manager at a Federally Qualified Health Center. Jamie received a Juris Doctor from Florida Coastal School of Law. Contact her via email at jmcintyre@hcfmv.com.

Comment

CMS Attempts to Shift Risk and Cut Costs in Medicare Part D: How CMS's New Modernization Model Holds Up

Rachel Park

ABSTRACT: Medicare Part D spending has been accelerating faster than all other components of Medicare. In response, CMS announced the Part D Payment Modernization model set to begin in January 2020. This voluntary five-year model (2020-2024) is a direct response to the "President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," which seeks to advance President Trump's "commitment to lower prescription drug prices. This Comment examines the risk structure and reinsurance subsidy calculations for Medicare Part D and the measures CMS has initiated in its Part D Payment Modernization Model.

Rachel Park, *CMS Attempts to Shift Risk and Cut Costs in Medicare Part D: How CMS's New Modernization Model Holds Up*, J. Health & Life Sci. L., Oct. 2019, at 48.

Medicare Part D and CMS's New Modernization Model

ARTICLE CONTENTS

INTRODUCTION

In 2013, Medicare spent almost $65 billion on Part D, which uses private insurers to provide prescription drug benefits to participants.[1] Participating private insurers bear part of the insurance risk of enrollees with Medicare sharing some of the risk with risk corridors in place to incentivize private insurers to participate. CMS risk adjusts direct subsidy payments to counteract private insurers avoiding enrollees who use more medication. In addition, Medicare reinsures 80% of covered spending above Part D's catastrophic threshold.[2] Risk corridors limit each plan's overall losses and profits if actual spending is higher or lower than anticipated, which provides protection for private insurers in the event aggregate drug spending is considerably above the amount anticipated.

Medicare Part D spending has been accelerating faster than all other components of Medicare, "rising 49% from 2010 to 2017," and experts say the program's structure is contributing to this increase.[3] Direct subsidy payments, in which Medicare bears the most insurance risk, grew by a cumulative 12% between 2007 and 2013, while reinsurance spending grew 143%.[4] According to the Medicare Payment Advisory Commission (MedPAC), the independent congressional agency, these increases "suggest that [private insurers] have been less successful at cost containment when they faced less risk for benefit spending."[5] In addition, Medicare pays the cost for enrollees with low incomes through Part D's low-income subsidy (LIS). This aspect of the Part D program tends to be costly because beneficiaries receiving LIS tend to be in poorer health and use more prescription medications.

MEDICARE PART D OVERVIEW

Medicare Part D is a voluntary prescription drug program for people with Medicare with benefits provided by private plans with federal government approval. Medicare beneficiaries have the option to enroll in a standalone Medicare Part D plan for prescription drug coverage or enroll in a Medicare Advantage plan, which includes prescription drug coverage. In 2018, more than 43 million of the 60 million people with Medicare were enrolled in

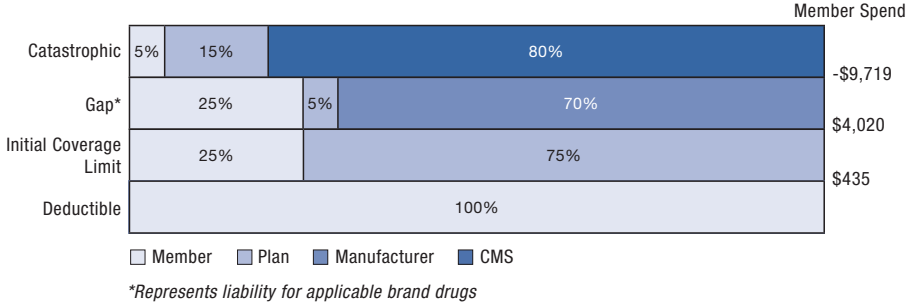
1 Joseph Walker & Christopher Weaver, *The $9 Billion Upcharge: How Insurers Kept Extra Cash from Medicare*, Wall St. J., Jan. 4, 2019.
2 MedPAC, Report to the Congress: Medicare and the Health Care Delivery System 139–40 (June 2015), http://www.medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.
3 Joseph Walker & Christopher Weaver, *The $9 Billion Upcharge: How Insurers Kept Extra Cash from Medicare*, Wall St. J., Jan. 4, 2019.
4 MedPAC, Report to the Congress: Medicare and the Health Care Delivery System 140 (2015).
5 *Id.*

Part D plans.[6] Part D plans offer either a defined standard benefit or an alternative of equal value.[7] In 2019, the Part D defined standard benefit "has a $415 deductible and 25% coinsurance up to an initial coverage limit of $3,820 in total drug costs []."[8]

The Medicare Part D coverage gap, often referred to as the Medicare doughnut hole, lies between the initial coverage limit and the catastrophic coverage threshold. A person enters the coverage gap when the total prescription spending (of both patient and plan) reaches a defined coverage limit. While in this coverage gap, enrollees pay 25% coinsurance for brand name medications. Manufacturer discounts during the coverage gap are credited towards the enrollees' true out-of-pocket costs (TrOOP), and once the TrOOP spending reaches the catastrophic coverage limit, beneficiaries' coinsurance is reduced to 5% for the remainder of the coverage year. This benefit cycle resets at the beginning of the following year and the process begins again.

When the enrollee is considered to be in the catastrophic coverage phase, the formulary drug costs are significantly reduced for the remainder of the year. For 2019, the catastrophic coverage threshold was $8,140. Once enrollees reach the catastrophic coverage phase, enrollees are responsible for 5% of total drug costs or a flat fee set annually, while plans cover 15%, and Medicare covers the remaining 80%. Due in part to the increasing number of Part D enrollees with spending above the catastrophic threshold, Medicare reinsurance payments for the catastrophic phase have accounted for a larger share of the total Part D spending, from 14% in 2006 to 42% in 2019.[9]

Exhibit 1. 2020 Part D Benefit Design



6 *An Overview of the Medicare Part D Prescription Drug Benefit*, Kaiser Family Found., Oct. 12, 2018, https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.
7 *Id.*
8 *Id.*
9 *Id.*

MEDICARE PART D BIDDING SYSTEM

Private insurers participate in Medicare Part D by submitting "bids" estimating the cost for providing the benefit for the coming year. Within Medicare Part D, there are two separate cost estimates, the "direct subsidy" and "reinsurance subsidy," which were designed by legislators creating Part D to entice private companies to participate in the new insurance market. Medicare uses these initial estimates to make monthly payments to the plans. At the end of the year, Medicare compares the plans' bids to their actual spending. This bidding system encourages private insurers to overestimate and underestimate in part of the bidding process to avoid loss of money.

For "direct subsidy" costs, which mostly covers routine costs, the private insurers and Medicare share the risk based on a complicated statutory formula. In this category, it benefits private insurers to overestimate in their initial bids. Underestimating in the bidding process results in loss of money for the private insurers. If the private insurer overestimates the costs, the insurer keeps some or all of the surplus.[10] If the extra money exceeds 5% of the original bid, the private insurer must pay a portion back to Medicare. In 2015, private insurers overestimated costs by about $2.2 billion and kept approximately $1.06 billion,[11] and from 2009-2013, 69% of Part D members were in plans that overestimated costs by at least 5%.[12]

On the other hand, for the "reinsurance subsidy," which covers government spending on a subset of patients in the catastrophic coverage phase, Medicare bears all of the risk. This leads to underestimations benefitting the participating insurers. Because the reinsurance subsidy bid is part of the total cost estimate driving member premiums, an underestimation here may help "hold premiums down with no risk to the insurer."[13] This heavily incentivizes underestimations since all costs will be fully reimbursed by Medicare. According to MedPAC, "plan sponsors have been able to keep part of catastrophic benefit spending out of enrollee premiums and receive the full reimbursement amounts due to them . . . [e]ven though the plan must return some of its [direct subsidy] profit to Medicare . . . it still nets a portion of profits."[14]

Medicare's reconciliation and risk corridor payments have revealed a consistent pattern of bidding too low for expected benefit spending above the catastrophic

10 Joseph Walker & Christopher Weaver, *The $9 Billion Upcharge: How Insurers Kept Extra Cash from Medicare*, Wall St. J., Jan. 4, 2019.
11 *Id.*
12 *Id.*
13 *Id.*
14 MedPAC, Report to the Congress: Medicare and the Health Care Delivery System 162 (2015), http://www.medpac.gov/docs/default-source/reports/chapter-6-sharing-risk-in-medicare-part-d-june-2015-report-.pdf.

threshold, and bidding too high for non-catastrophic benefits.[15] The statistical likelihood of these consistently inaccurate bids are very unlikely.[16] MedPAC has suggested considering changes to Part D's risk-sharing mechanisms to encourage private insurers to "better manage drug benefits for higher cost enrollees."[17] Since the inception of the Medicare Part D program, the structures of the coverage gap and the thresholds for different benefit phases have changed. However, the catastrophic coverage phase features the same liability percentages as originally outlined in the Medicare Prescription Drug Improvement and Modernization Act (MMA).[18] Changes to the subsidies or to the structure of the risk corridors would address this issue contributing to the increased spending in Medicare Part D. "Several program modifications may be necessary at the same time . . . to balance concerns about cost control and incentives for selection behavior."[19]

CMS ANNOUNCES NEW MODEL FOR MEDICARE PART D DRUG PRICING: "PART D PAYMENT MODERNIZATION" MODEL

In January 2019, CMS announced the Part D Payment Modernization model set to begin in January 2020. This voluntary five-year model (2020-2024) is a direct response to the "President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," which seeks to advance President Trump's "commitment to lower prescription drug prices, with Medicare beneficiaries, Part D plans, and CMS all benefitting from a more aligned system."[20] Participation in the model is voluntary; plans that desire to participate will submit an application to participate in the new Part D model. CMS will then select plans to participate.[21]

Under the Modernization model, eligible stand-alone Prescription Drug Plans (PDPs) and approved Medicare Advantage-Prescription Drug Plans (MA-PD) will assume "two-sided risk for CMS's federal reinsurance subsidy (80 percent of cata-

15 *Id.* at 141.
16 Joseph Walker & Christopher Weaver, *The $9 Billion Upcharge: How Insurers Kept Extra Cash from Medicare*, Wall St. J., Jan. 4, 2019.
17 MedPAC, Report to the Congress: Medicare and the Health Care Delivery System 141 (2015).
18 Glenn Giese et al., Oliver Wyman, Part D Catastrophic Coverage–Financial Implications of Restructuring Liability (2019), https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2019/may/Restructuring%20the%20CMS%20Federal%20Reinsurance%20Program.pdf.
19 MedPAC, Report to the Congress: Medicare and the Health Care Delivery System 142 (2015).
20 Press Release, CMS, CMS Announces New Model to Lower Drug Prices in Medicare Part D and Transformative Updates to Existing Model for Medicare Advantage (Jan. 18, 2019), https://www.cms.gov/newsroom/press-releases/cms-announces-new-model-lower-drug-prices-medicare-part-d-and-transformative-updates-existing-model.
21 CMS, Part D Payment Modernization Model Request for Applications CY 2020, https://innovation.cms.gov/Files/x/partd-payment-modernization-model-rfa.pdf.

strophic phase liability) . . . ."[22] CMS believes that by increasing plans' share of costs in the catastrophic coverage phase from 15% to 80%, private plans will be incentivized to encourage the use of drugs with lower list prices.[23] In addition, CMS will provide "programmatic flexibilities," such as "Part D Rewards and Incentives programs, to ensure Medicare beneficiaries are able to maintain affordable access to the prescription drugs that they need."[24]

After one plan year, CMS will retrospectively create a "spending target benchmark" representing the federal reinsurance subsidy that CMS would have paid to participating plans had they not participated in the model. The spending target benchmark will be developed using a "multivariate approach based on product type (PDP or MA-PD), percentage of enrollment that receive the low-income subsidy, non-model participating organization federal reinsurance trends, regional trends, organization [] risk adjustment scores, formulary and type of plan offering, and other factors as deemed appropriate by CMS."[25] CMS offers additional detail on the spending target benchmark methodology to provisionally approved organizations that indicate participation in the Modernization Model with their bid submissions for the 2020 plan year.[26]

Under the Modernization Model, CMS will share savings on federal reinsurance subsidy spending relative to the spending target benchmark. If the plan's federal reinsurance subsidy spending is lower than the calculated benchmark, then the plan will receive "performance-based payments, based on the total percent saved."[27] CMS will share "30[%] of any savings up to 3[%] of total federal reinsurance subsidy spending savings, and 50[%] of any savings above 3%."[28] On the other hand, if the plan's federal reinsurance subsidy spending is higher than the target benchmark, the plan must repay a 10% penalty of the difference from any additional spending above the target benchmark. Essentially, participating insurers share in savings if they stay below the target but are accountable for losses if they exceed the calculated target.

In addition, CMS will allow participating plans to propose "clinically-based drug utilization management techniques" to increase the availability of prescription drugs

22 *Part D Payment Modernization Model Fact Sheet*, CMS (last updated July 30, 2019), https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/.
23 Kelly Davio, *New Medicare Part D Model Will Shift More Risk to Plans*, Ctr. for Biosimilars, Jan. 22, 2019, https://www.centerforbiosimilars.com/news/new-medicare-part-d-model-will-shift-more-risk-to-plans.
24 *Part D Payment Modernization Model*, CMS (last updated July 30, 2019).
25 CMS, Part D Payment Modernization Model Request for Applications CY 2020, at 3–4.
26 *Id.*
27 Press Release, CMS, Part D Payment Modernization Model Fact Sheet (Jan. 18, 2019).
28 CMS, Part D Payment Modernization Model Request for Applications CY 2020, at 4.

with lower list prices while also ensuring maintained access.[29] Plans will be granted this added flexibility to create a Part D Rewards and Incentive Program to "strengthen the clinical relationship between their enrollee and the enrollee's provider, and his or her chosen Part D plan."[30] CMS provided some examples of these goals in the Part D Payment Modernization Model Overview Webinar, stating they include rewarding and incentivizing patient participation in disease management programs, medication therapy management with pharmacists or providers, and active engagement with plans to understand medications, including clinically-equivalent, cheaper alternatives.[31] It is unclear what exactly these programmatic flexibilities will look like and how they will work to achieve the listed goals; however, CMS has stated the details of the additional programmatic flexibilities will be outlined to participating plans.

Of note, all current Part D payment and reconciliation processes remain the same under the Modernization Model, including the application of risk corridors. According to CMS, plans "will continue to bid a prospective federal reinsurance amount, which will be fully reconciled as per current law . . . . Payment, risk adjustment, and reconciliation processes will still apply to each subsidy consistent with current law."[32] With no changes to the reconciliation of reinsurance and direct subsidy amounts, it is uncertain how much the Modernization model will impact overall spending by Medicare for Part D.

MODERNIZATION MODEL'S EFFECT ON OVERSPENDING IN MEDICARE PART D

The law currently allows Part D plans great discretion in designing formularies, which was intended to encourage private insurer competition. Plans are active in designing their formularies (the list of drugs covered) and have relative freedom to choose which drugs are listed as covered, what tiers they are categorized in, out-of-pocket cost designations for tiers, and other drug-specific non-price hurdles.[33] No plan covers all prescription drugs, and different plans may charge different copays for the same drug. Plans may also change their formularies and costs (premiums, deductibles, copays) every calendar year. Without changing the degree of freedom plans exercise in determining eligibility and pricing of available drugs, it is uncertain whether lowering drug prices and reducing out-of-pocket costs will come as a result of measures benefiting the private insurers.

29 Press Release, CMS, Part D Payment Modernization Model Fact Sheet (Jan. 18, 2019).
30 *Id.*
31 CMS Innovation Center, Part D Payment Modernization Model: Model Overview 16, https://innovation.cms.gov/Files/slides/partd-payment-modernization-overview_slides.pdf.
32 Press Release, CMS, Part D Payment Modernization Model Fact Sheet (Jan. 18, 2019).
33 Joseph Walker & Christopher Weaver, *The $9 Billion Upcharge: How Insurers Kept Extra Cash from Medicare*, Wall St. J., Jan. 4, 2019.

Whether Medicare is able to lower the amount it pays in federal reinsurance subsidy under the efforts of the Modernization Model seems to depend in large part on the calculation of the spending target benchmark and its accuracy in setting a reasonable level of spending. If the calculated spending target benchmark is too low, private insurers may cut benefits or reduce availability to compensate for the fees they will have to pay under the Model. On the other hand, if the benchmark is too high, the program will be ineffective in incentivizing participating plans to decrease spending. As a whole, the Modernization Model seems to project only surface level modifications that may superficially reduce consumer costs at the price of reduced coverage or decreases in benefits. The fear is that participating plans will alter formularies to reduce overall patient coverage to stay below the spending target benchmark for the federal reinsurance subsidy. It is still early in the process, and it remains to be seen what the "additional programmatic flexibilities" will achieve in terms of lowering Medicare spending on Part D.

In the end, this Modernization Model and the rewards and penalties for actual spending in comparison to the benchmark amount only apply to participating plans. Plans that voluntarily choose to be part of the Modernization Model will dictate the spending target benchmark, and the rewards and penalties of the modernization effort will only apply to plans that choose to participate. It is questionable if the voluntary incentive model will actually work to reduce costs, especially if the bidding and reconciliation process for both Part D subsidy categories will remain the same. With the risk adjustments and reconciliation process remaining untouched by the Modernization Model, the incentives to under- or overbid may endure. It is uncertain whether the Model, with the calculated spending target benchmark, will become mandatory and applicable to all private insurers in the Medicare Part D market.

WHAT DOES THIS MEAN FOR HEALTH CARE COMPANIES?

At the moment, this Modernization Model does not affect many people or health care entities. Unless a private insurer is participating in the voluntary Modernization Model, they are not affected by the program, and all risk adjustments and reconciliation processes will be unchanged.[34] Depending on how the Modernization Model plays out, it may be applied to all plans participating in Medicare Part D. The fact that Medicare Part D was designed precisely to encourage private insurer participation reveals the precarious nature of this problem and the balance between curbing Medicare Part D spending and ensuring sufficient Medicare prescription benefit coverage. J

34 Press Release, CMS, Part D Payment Modernization Model Fact Sheet (Jan. 18, 2019).

Author Profile

RACHEL PARK is a first-year law clerk in the health care practice of Norton Rose Fulbright LLP in the Washington, DC office. Throughout law school, she has worked as a legal intern at several organizations in the health industry, including the American Health Lawyers Association, Doctor on Demand, and the Centers for Medicare and Medicaid Services. She graduated from George Washington University Law School in 2019 and completed her undergraduate degree at Northwestern University in 2014. Contact her via email at rachel.park@nortonrosefulbright.com.

Comment

State Civil Commitment Laws: A White Paper

American Health Lawyers Association

ABSTRACT: On April 24, 2019, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the American Health Lawyers Association hosted a convener session on state civil commitment law issues. Experts from around the country gathered for a day-long meeting to identify the most pressing issues and discuss possible solutions. The participants in attendance represented a diversity of backgrounds, expertise, and viewpoints on the issue. Convener participants were all individuals who handle matters related to state mental health laws, and they presented their individual viewpoints on the subject.

American Health Lawyers Ass'n, State Civil Commitment Laws: A White Paper, J. Health & Life Sci. L., Oct. 2019, at 58.

State Civil Commitment Laws

ARTICLE CONTENTS

INTRODUCTION

The American Health Lawyers Association (AHLA) hosts nonpartisan expert panel convener sessions in order to provide a neutral forum for the frank and candid exchange of views and analyses among invited experts on select health care policy issues that have a clear legal nexus. White papers and supplemental resources often result from these convener sessions. These sessions underscore AHLA's commitment to promote a better understanding of health care issues and to encourage constructive dialogue among all affected industry stakeholders, government, academia, and the lay community.

On April 24, 2019, the Substance Abuse and Mental Health Services Administration (SAMHSA) and AHLA hosted a convener session on state civil commitment law issues. Experts from around the country gathered for a day-long meeting to identify the most pressing issues and discuss possible solutions. The participants in attendance represented a diversity of backgrounds, expertise, and viewpoints on the issue. Convener participants were all individuals who handle matters related to state mental health laws, and they presented their individual viewpoints on the subject.

This white paper captures the major themes and recurring issues that convener participants–with their diverse experience, expertise, and perspectives–discussed and debated during the day-long session. It offers a range of feasible and practical options and solutions that were suggested as a result of the healthy dialogue that took place–options and potential solutions that political leaders, community activists, and patient advocates may want to consider and tailor to the current needs of their communities. Given the nature of convener discussions, this white paper includes statements that reflect everything from a broad consensus of all participants to the view of an individual participant.

Civil commitment is the legal process by which a judge can order an individual with a serious mental illness to be confined against his/her will or compelled to receive outpatient treatment. State civil commitment laws play an important role in mental health care systems. The civil commitment process is often viewed as a last resort to helping an individual access necessary treatment.

This article will discuss suggestions for how states can (1) reduce the number of civil confinements and (2) improve the civil commitment process. Ultimately, states should strive to decrease its number of civil commitment incidents and increase its focus on developing comprehensive systems of community supports to address mental health services. What can policymakers do to create a robust, community-based

system that helps individuals avoid involuntary detention? What does a system with less fragmentation and increased access to services look like? How can policymakers be convinced to spend scarce public resources to implement reforms?

Comprehensive mental health systems are currently the exception in the U.S., making civil (i.e., involuntary) commitment necessary to ensure that individuals with serious mental illness receive prompt and much needed care. The laws and procedures that govern the process of civil commitment must ensure that individuals with mental illnesses are treated with dignity. Currently, there is no consensus on how state laws can strike the right balance between protecting the civil rights of individuals while also providing timely access to care. States are struggling to do the following while also addressing the issues that may arise in pursuing these goals within their existing legal frameworks: (i) effective implementation of court-supervised treatment programs; (ii) safe transportation of individuals suffering a mental health crisis; (iii) use of the civil commitment process for individuals with substance use disorders; and (iv) data collection on patient outcomes.

While this article does not provide a panacea that will make mental health care systems or the civil commitment process work better, it does provide suggestions that may be helpful for policymakers to consider.

PRE-CIVIL COMMITMENT ISSUES

Improving Access and Treatment: The need for improved access to various treatment modalities and services is clear. States should evaluate what services this patient population needs and where services may be lacking. The issue is not necessarily about keeping individuals out of certain types of facilities but rather, ensuring that a continuum of care can provide individuals with clinically appropriate, evidence-based services. When an appropriate treatment or service is unavailable, other levels of care become disrupted due to a bottleneck effect, *i.e.*, an increasing number of patients awaiting treatment that is unavailable or in short supply. A range of community-based treatment options already exist beyond involuntary commitment. In addition, an individual's needs and preferences change over time; it is important to keep in mind the fluidity of the human condition, especially when dealing with one's mental health.

Disparate options are available to those living with serious mental illness depending on where they live in the country. Some states have more robust treatment options than others. The availability of options is widely determined by a state's Medicaid funding (*i.e.*, whether the state is a Medicaid expansion state or not), as well as the

criminal justice system's role in diverting people to mental health care facilities rather than incarcerating them. A large percentage of this patient population is on Medicaid, Medicare, or otherwise uninsured. Expanding coverage for mental health treatment and services through federal health care programs must be part of any long term solution that aims to increase access to mental health care.

Discussion about the barriers that exist for patients receiving institutional care is ongoing. Under the Institutions for Mental Diseases (IMD) exclusion, states are forbidden from using federal Medicaid funds to reimburse inpatient mental health and substance use disorder facilities with more than 16 beds that provide treatment for non-geriatric adults. Medicare beneficiaries are also capped to 190 days of inpatient psychiatric care in their lifetime.

Several newer options are available for states to obtain a waiver of the IMD exclusion that may assist in expanding capacity for residential care. Yet, only a few states have applied for these waivers as of the date of this article's publication.

A lack of funding is a major obstacle to increasing the availability of treatment options. Many states face bed shortages that disrupt the health care system. As the number of public psychiatric hospitals continue to shrink, more individuals with serious mental illness are left untreated or must seek inadequate treatment from hospital emergency room departments. Funding issues also disrupt the continuity of care. A lack of resources has been cited as a reason for high employee turnover at facilities, resulting in patients having to frequently start new relationships with different social workers, psychiatrists, and therapists. Finally, uncertainty over whether Medicare or Medicaid will reimburse providers can result in patients not receiving services when transitioning out of inpatient facilities.

States should consider providing more community-based programs, coupled with social services, to individuals with mental illnesses. Resources related to housing, transportation, and employment-related assistance are needed just as much as health care services and should be made available to this patient population. Making these services accessible is one of the most effective ways to keep people with mental illnesses out of hospitals and jails. A common suggestion is to make it clear that these social services are reimbursable. Other suggestions for reducing civil commitments include:

- Using early intervention programs in schools and primary care programs (*i.e.*, screening, brief intervention, and referral to treatment) to help persons receive care before a mental health crisis occurs.

- Increasing the use of alternative payment models to help improve patient outcomes.
- Using mental health courts and other court-supervised treatments as a way to divert patients from jail or sporadic crisis-based inpatient treatment, and into options with more longevity and resources for stability.

Preserving Autonomy and Psychiatric Advance Directives: Psychiatric advance directives are a potential way to preserve patient autonomy and make their wishes known. An advance directive or mental health power of attorney enables a person who anticipates a potential mental health crisis to draft a document setting out how the individual would prefer to receive treatment in a crisis.

Although the Centers for Medicare & Medicaid Services (CMS) has recognized the importance of psychiatric advance directives since 2006, their use is uncommon. There have been instances where hospitals have delayed providing someone with inpatient treatment because staff did not understand how an advance directive works.[1] Health care providers and state policymakers can take action to facilitate their use, and states should consider providing more education and training about advance directives.

For example, one recommendation is that states adopt legislation that explicitly permits the use of advance directives, as opposed to validating them through other applicable laws.[2] Specific laws can assist with education efforts for clinicians, particularly if the advance directive was made a component of community-based treatment programs for those with a chronic mental health condition.

Facilities must also be aware of when an individual has an advance directive. This issue in particular surfaces when a patient is transferred between facilities. An advance directive must be in a patient's electronic medical record and each health care provider must have access to the same document for it to be effective. It is important therefore that advance directives are included in health information exchanges.

1 Regardless of whether an advance directive is explicitly permitted by state law, facilities receiving Medicare and Medicaid reimbursements are required to recognize advance directives for behavioral health. *See* SAMHSA, Advance Directives for Behavioral Health, https://www.samhsa.gov/section-223/governance-oversight/directives-behavioral-health (last updated May 17, 2019).

2 "Currently, 25 states have laws that permit psychiatric advance directives. For states that do not, an individual can still draft a PAD under the more general statutes connected to health care directives, or Living Wills" according to the National Alliance on Mental Illness. *See Psychiatric Advance Directives (PAD)*, NAMI, https://www.nami.org/Learn-More/Mental-Health-Public-Policy/Psychiatric-Advance-Directives-(PAD) (last visited Sept. 15, 2019).

THE CIVIL COMMITMENT STANDARD

While most mental health services and treatments are provided voluntarily, civil commitment is widely viewed as necessary under certain circumstances. These laws can prevent the negative consequences that may occur when an individual who is a danger to him/herself or others goes without treatment. Every state has adopted laws that stipulate when someone can be involuntarily committed; however, there are considerable differences between these laws.[3] For example, nearly every state has a law that says individuals who are "dangerous to self or others" can be subjected to involuntary inpatient treatment. But several states have expanded their commitment laws to allow "serious deterioration" as a separate standard.[4] Regardless of the language used, every state permits involuntary commitment for individuals who are unable to take care of their basic needs because of mental illness.

States should consider whether using the word "dangerousness" in their standards for civil commitment creates a stigma for mental illness. Most people still believe that an individual must be dangerous in order to be committed into a mental hospital, even though many states have moved away from this being the only criterion for commitment. States could potentially remove the word "dangerousness" from their statutes without effectively changing how their civil commitment standards are applied.

There is also some dispute over whether lowering the threshold for inpatient commitments improves access to care. It has been suggested that when the commitment standard is set below "medical necessity," it has very little impact on who gets committed. State law almost always requires a medical professional's opinion to support commitment. Psychiatrists and psychologists are unlikely to recommend involuntary commitment when it is not considered medically necessary because it would contravene their professional obligations and likely violate insurance and Medicaid policies that will not pay hospitals for admitting patients at a lower standard.

Yet, the standard could still influence who comes into the commitment pipeline. Commitment cases are initiated for a variety of reasons. Family members and others often consider this standard before starting the process. Thus, the standard can become a way to get an individual access to care even in cases where ultimately there is not a commitment hearing.

3 American Health Lawyers Ass'n, Mental Health Statutes: A 50-State Survey (2019).

4 SAMHSA, Civil Commitment and the Mental Health Care Continuum: Historical Trends and Principles for Law and Practice (2019), https://www.samhsa.gov/sites/default/files/civil-commitment-continuum-of-care.pdf.

MODEL CIVIL COMMITMENT LAW

Given the wide variations between state laws, a model law could be a useful reference for legislators.[5] States have different rules and procedures related to several parts of the civil commitment process, including the length of time an individual may be held in custody before a psychiatric evaluation occurs and when hearings must happen, but it is difficult to generate consensus on what a model law should look like. In addition, civil commitment laws are not uniformly applied within states. Therefore, even if a great law existed, there would still be significant variations on how it is interpreted and implemented. Drafting a model law also may be premature because there is not enough data to support what types of standards and procedures work best.

IMPROVING THE CIVIL COMMITMENT PROCESS

Training and Education: Overcoming the stigma associated with civil commitment is challenging but critical to helping communities understand that the concept of civil commitment adds to the dignity and increases the rights of individuals with serious mental illness. Civil commitment, which may often be portrayed as denying someone their civil liberty, can be the tool that provides an individual the right to receive needed care and treatment, as well as the means to protect the individual from harming him/herself or others.

A common suggestion for improving the civil commitment process is to provide more cross-training about the legal system between the different disciplines of health care providers, such as physicians, therapists, nurses, and other clinicians; and likewise providing attorneys and judges with more training about the health care system.

Increased cross-training can help everyone recognize when the involuntary commitment process needs to take effect, including the additional opportunities the system has for a patient so that future crisis interactions can be avoided. Such increased cross-training can also reduce conflicts between clinical staff and legal professionals. One consideration to take into account in efforts to increase cross-training amongst and between the various clinicians and legal professionals is having states approve more online and on-demand classes for professional continuing education credits.

5 One participant noted there has not been a significant push towards drafting a uniform law since the American Psychiatric Association published its model civil commitment law in 1982.

Forced Medication: Another issue that states must consider is the use of medication. One idea to consider is that courts resolve medication-related issues during civil commitment hearings to avoid delaying treatment to patients. Many of these patients need medication to help them get through a mental health crisis, and the longer they wait for treatment, the more harm they suffer.

Typically, a patient does not get better simply by being in a psychiatric unit without medication. Deciding medication-related issues during a separate hearing may open the door for judges and attorneys to second guess decisions that are best left to the doctors. However, a patient's treatment preference should not be disregarded out of hand. It is important to recognize that civil commitment and forced medication are two distinct legal issues. Health care providers must understand that patients can refuse treatment under certain circumstances. Sometimes the best way to resolve medication-related issues is for health care providers to work with patients and their counsel to find a solution.

Transportation: For many patients, the civil commitment process begins in an emergency department and yet, there are numerous reasons to move patients out of this setting as quickly as possible. Emergency departments are not ideal therapeutic environments (bright lights, high noise level, lots of activity) for individuals experiencing a mental health crisis. In addition, the patient experiencing such a crisis often does not receive immediate, necessary, and active treatment and care. However, transporting patients between facilities during the civil commitment process can be a burdensome and challenging issue for states and private hospitals for several reasons:

- Lack of available beds at inpatient facilities
- Disputes over who is responsible for moving the patient
- The proximity between facilities in large rural states
- Issues related to transferring a patient with dignity

States vary on who is authorized to transport individuals during a mental health crisis. For example, some states exclusively rely on law enforcement to transport patients. Conversely, other states permit transportation by non-law enforcement, such as emergency responders and dedicated crisis response units.

Law enforcement agencies spend an extraordinary amount of time and resources transporting individuals with mental illnesses.[6] Some of these individuals are not actively dangerous, thus eliminating the need for law enforcement to perform this task; however, ambulances and stretcher vans are either too costly or considered inadequate alternatives given the patient's legal status of emergency detention and inability to refuse transfer to the psychiatric facility.

Relatedly, concerns have been raised over the use of handcuffs and marked police cars to transport patients. State law should ensure that patients are transferred with dignity, particularly in situations involving minors and elderly adults. One suggestion is for states to adopt frameworks that permit transportation in unmarked vehicles with plain clothes officers and mental health techs trained in crisis intervention. States can also tackle transportation-related issues by requiring local municipalities to develop transportation plans with input from law enforcement agencies, hospitals, and other stakeholders. Other considerations for improving the commitment process:

- A person's dignity must be considered during civil commitment hearings, regardless of what guardians and legal representatives have planned for meeting the person's needs. Counsel participating in involuntary hearings should be mindful to avoid paternalistic thinking that they know what is best for the patient in the absence of the patient's ability to self-promote his or her own wishes.
- A treating physician's testimony during a hearing can have an adverse impact on the patient-physician relationship. Allowing a non-treating physician to perform a psychiatric evaluation and subsequently testify about the results is a potential way to preserve this relationship; however, this option may not always be available because it requires additional staffing and resources. Obtaining a psychiatric evaluation by a non-treating physician can also make it more difficult to present evidence in support of committing an individual. As a best practice, physicians should inform their patients about the reasons for an evaluation and the possibility that they might have to testify about the results of such an exam.

6 Law enforcement spends almost a billion dollars every year transporting individuals, a participant said.

CIVIL COMMITMENT AND SUBSTANCE USE DISORDERS

There are divergent views over whether civil commitment proceedings should be used for individuals with substance use disorders. The opioid epidemic has raised awareness of drug addiction issues. As a result, more state resources are being used for patients with substance use disorders; however, the opioid epidemic has not necessarily led to more involuntary commitments.

Addiction and the involuntary commitment process are not easily squared. While some states' laws allow for the process to be utilized in severe cases of addiction, practitioners (physicians and lawyers alike) rarely encounter the process used to place someone in treatment against their will. There is a lack of appropriate placement facilities for substance use disorders. In addition, and most controversial, clinicians find it difficult to confidently determine whether addiction has overridden a person's free choice.

Substance use disorders can be life threatening. Individuals who have addiction issues may fall under already existing civil commitment standards. Someone who has overdosed multiple times may not be able to take care of his/her basic needs, and thus be subject to involuntary commitment; however, concerns have been raised over whether explicitly including substance use disorders disincentivizes a person from voluntarily seeking treatment.

When the civil commitment process is used in instances involving substance use disorders, there must be clear and firm standards that protect the individual's civil rights, but some have questioned whether commitment proceedings for these types of situations should have different standards and procedures.

Substance use disorders and other types of mental illness often co-occur. It can be unclear whether the underlying disability is drug addiction or another mental illness. Creating separate civil commitment rules and procedures for substance use disorders may cause hearings to become too focused on deciding an individual's diagnosis, whereas commitment hearings should be focused on whether an individual needs treatment for a mental illness. Moreover, creating a separate process could also add stigma to addiction issues without expanding access to meaningful treatments. Further, many believe the use of the drug court model is an important tool in the case of substance use disorders, particularly given the volume of interaction with the criminal justice system and substance use disorder cases.

ASSISTED OUTPATIENT TREATMENT, MENTAL HEALTH COURTS, AND OTHER DIVERSION PROGRAMS

Nearly every state now has laws that permit assisted outpatient treatment (AOT) for persons who meet certain criteria. AOT allows courts to order individuals with severe and impairing mental illness into community-based treatment programs. Typically, outpatient commitment laws are aimed at individuals who have a history of not complying with treatment and who have a history of serious impairment as a result of untreated mental illness that endangers them or others.

AOT has been demonstrated to reduce hospitalizations and arrests, and it provides another option to help patients get access to care. However, some states still have not provided the structure or resources to make AOT effective. Moreover, questions exist about whether courts can hold patients accountable for failing to follow through with their treatment plans. In many states, AOT relies on a "black robe effect" to encourage individuals to comply with recommended treatment. Some will refuse treatment just because that treatment is required by a court order, but a court order can be of assistance in helping individuals make a decision about participating in recommended treatment. Some suggestions related to AOT implementation include the following:

- Provide judges with quick reference guides about inpatient and outpatient laws. Provide treatment teams with a companion manual.
- Obtain more data about how AOT, mental health courts, and diversion programs can be more effective.
- Free up beds by connecting forensic patients to services in their community, rather than having them wait in hospitals for competency examinations.
- Require law enforcement agencies to provide to mental health courts a list of those participating in AOT and who have been arrested. Doing so can help ensure that individuals with mental illness receive treatment, and it can also help the courts track individuals in their programs.

THE NEED FOR MORE DATA

The theme for which there was universal agreement was the need for more data and information about what can be done to engage this patient population with meaningful treatment and services. It is difficult to advocate for this patient population because

of a lack of data points that describe the current situation for the most seriously mentally ill who are not able to access the treatment system effectively.

More data can help measure whether states are improving patient outcomes or whether resources are being used effectively. State collection of data on recidivism rates–how frequently individuals are incarcerated or placed in inpatient facilities and hospitals–may be a useful data collection point.

Data can also play an important role in convincing policymakers that certain health care reforms are needed. One consideration is making the "business case" to legislators that it is fiscally responsible to take a course of action. This patient population takes a significant amount of resources away from the system. By engaging this patient population, states can generate cost savings.

Hospitals have developed programs to address the 5% of the population that takes 50% of the emergency department resources, and a similar concept could be applied to a community-wide mental health program. Having a data sharing construct that enables a case manager to follow a targeted group of persons with frequent interactions with law enforcement, hospital emergency departments, and psychiatric units–ensuring that they are connected to all available community resources–could help avoid the costly, cyclical, and often traumatic crisis interventions.

However, policymakers should not simply consider cost neutrality. For example, there has been some pushback related to whether mental health courts are a less expensive solution than incarcerating an individual; however, the role of government is to assist its citizens.

Incarceration is associated with a substantial risk of not receiving treatment for a mental illness which contributes to adverse outcomes for those individuals including a worsening of illness and development of a mental illness that may be more difficult to treat with currently available medications and therapies. Therefore, not every decision should be based on cost alone.

CONCLUSION

Civil commitment is a powerful tool that may be used by states to provide those living with serious mental illness care and safety. Civil commitment laws vary greatly and come with many considerations for states and local organizations. Ideally, the goal is to have a comprehensive and robust system of mental health care to intervene early and avoid civil commitment. In the absence of such a system, we must rely on civil commitment as a necessary tool and do all we can to ensure it is implemented as effectively as possible. J

Brief Insight

Risky Hospital Laboratory Billing Arrangements: A Sad Tale of Greed and Its Consequences for Small Hospitals and Their Communities

Jane Pine Wood

ABSTRACT: During the past several years, similar risky hospital laboratory billing arrangements were promoted to small and rural hospitals as "safe" revenue enhancement opportunities. Pursuant to these arrangements, the hospitals billed private payers for laboratory services that were performed by third party laboratories (often out of state) for patients (also often out of state) who had not received any other services from the hospitals. The role of the hospitals was to utilize their contracts with third party payers. Because the billing arrangements did not involve government payer work, the participants apparently believed the risk was minimal or non-existent. However, private payers took aggressive action against the billing hospitals to recoup payments based upon various legal and contractual bases, including false claims and breach of contract. As a result of the payer actions against the billing arrangements, a number of the hospitals were forced into bankruptcy or sale.

Jane Pine Wood, *Risky Hospital Laboratory Billing Arrangements: A Sad Tale of Greed and Its Consequences for Small Hospitals and Their Communities*, J. Health & Life Sci. L., Oct. 2019, at 72.

Hospital Laboratory Billing Arrangements

ARTICLE CONTENTS

INTRODUCTION

Approximately five years ago, numerous members of the health care bar began receiving calls from laboratories, small community and rural hospitals, and marketing companies to solicit legal advice regarding very similar billing arrangements for laboratory services. The apparent goal of most of the proposed arrangements was to leverage the third party payer contracts of the hospitals so that laboratory testing services of out-of-network laboratories could be billed through the hospitals' payer contracts. The promoters of these billing schemes and their legal counsel claimed that because no federal payers were involved in the arrangements, there was little or no risk to the parties involved.

At the time, numerous lawyers advised that while there may be differing opinions as to whether proposed arrangements constitute clear violations of federal or state laws or statutes, the hospitals were at significant risk of recoupment of amounts paid by the third party payers based on lack of medical necessity for the testing, breach of contract, or false claims theories. These lawyers shared concerns that the third party payers would decline to contract with the laboratory for specific business reasons, and would push back if they learned that the parties collaborated to hide the identity of the performing laboratories and utilize the hospitals' in-network contracts. In particular, the hospitals' private payer contracts likely limited reimbursement for laboratory services that were either provided by the hospital's own laboratory or were provided to patients of the hospital. Furthermore, there was risk that some of the arrangements could be considered to be in violation of federal and/or state laws.

For some of these small town and rural hospitals, the lure of "easy" dollars was tempting. Many such hospitals have closed over the past decade, victims of rising costs and declining reimbursements, as well as changing demographics. The potential additional revenue promised by the promoters of the arrangements could be significant to these hospitals, enabling them to avoid cuts in services and/or staffing. In addition, given the tight budgets of these hospitals, many have limited access to the counsel of health care lawyers who would have been equipped to advise of pitfalls in the arrangements.

Unfortunately, for the mostly small town and rural hospitals involved in these schemes and the communities they served, the predictions that many legal observers made were accurate. Vulnerable hospitals faced financial doom, with some closing their doors in the wake of recoupments and lawsuits filed by third party payers. Communities have been deprived of access to hospital care. The story of these billing schemes is an important reminder that even if an arrangement does not clearly violate a law or statute or only involves services covered by non-government third party payers, attorneys should be cautious about advising clients that the arrangement bears

little risk if the intent is to circumvent third party payer contracts and policies. Third party payers are increasingly proactive and aggressive in taking legal action when they believe that health care providers are improperly seeking reimbursement for services.

STRUCTURE OF BILLING ARRANGEMENTS

The billing arrangements involving hospitals, laboratories, and marketing companies shared the same basic structure. A laboratory marketing company would approach a rural or small community hospital with an opportunity to profit on billing for laboratory services–typically toxicology and/or pharmacogenetic testing–by leveraging the hospital's in-network payer contracts. The patients who received the laboratory testing were not patients of the hospital, but rather were patients generated by the marketers in distant markets, often different states from the hospital. An independent laboratory that did not hold third party payer contracts performed the testing services and billed the services to the hospital. The hospital then rebilled the laboratory services with a markup in price under its third party payer contracts. The hospital would realize a profit based on this markup in price and the marketers were paid a commission either by the performing laboratory or by the billing hospital for the marketing of the testing.

Some of the hospitals seemed unaware of the billing risks involved, particularly with respect to medically unnecessary services, breach of payer contract risks, and possible allegations of fraudulent services. These hospitals relied on representations from the promoters of the arrangements that the arrangements did not clearly violate specific laws and/or that no government payer work was involved. Some hospitals were managed by hospital management companies who proposed and implemented the laboratory billing arrangements as a way to generate revenue. At least one management company was compensated based on the revenue growth of the hospitals, so an arrangement that increased hospital collections (whether legally questionable or not) may have had additional attractiveness to the management company.

PUTNAM COUNTY MEMORIAL HOSPITAL

An example of the billing arrangement involved Putnam County Memorial Hospital. Facing bankruptcy in 2016, a hospital management company, Hospital Partners, took over the operations of the 25-bed critical access hospital. As reported by CBS News in a May 16, 2018 investigative report[1] and National Public Radio in a July 3, 2018

1 *Auditor "Shocked" by Massive Billing Schemes at Rural Hospitals*, CBS News (May 16, 2018), https://www.cbsnews.com/news/questionable-billing-schemes-rural-hospitals-costing-health-insurance-companies-millions/.

report,[2] as well as summarized by Nicole Galloway, the Missouri State Auditor,[3] Hospital Partners introduced laboratory billing through a related company, Hospital Laboratory Partners, using the payer contracts of Putnam County Memorial Hospital to bill for laboratory testing performed by other laboratories. In a six-month period, Putnam Country Memorial Hospital's revenues swelled to $92 million, compared to $7.5 million the year before, according to the audit by the Missouri State Auditor's Office. Eighty percent of the revenue reportedly went to others besides the hospital in the form of payment to the performing laboratories for the purchased laboratory testing (some of the laboratories had ties to the management company), compensation to a billing company affiliated with the management company, and management fees to the management company itself.

The State Auditor reported that from November 2016 through February 2017, Putnam Country Memorial Partners collected $19.8 million for laboratory billings received, but the originating activity was for out-of-state patients for laboratory testing that was not performed in Putnam County. According to the report,

> Hospital officials have not provided sufficient support to justify why such activity is being billed through the hospital . . . . During the audit, the State Auditor's Office was contacted by the fraud examiner of a private insurance company in Florida that had recently denied claims of approximately $700,000 from the hospital due to the excessive cost of the claims, a lack of documentation to support the claims, and indications the billings may be fraudulent. This individual referred us to a fraud investigator for a second, much larger, private insurance company who stated payments of up to $4.3 million in what the company considered fraudulent claims had been paid to the hospital in recent months. Based on this information, the second insurance company is no longer paying any claims from the hospital because the billings submitted are pass-through billings, which are indicative of a fraud scheme.[4]

2 Dan Margolies & Bram Sable-Smith, *Vulnerable Rural Hospitals Face Tough Decisions on Questionable Billing Schemes*, NPR (July 3, 2018), www.npr.org/sections/health-shots/2018/07/03/617876814/vulnerable-rural-hospitals-face-tough-decisions-on-questionable-billing-schemes.

3 Nicole Galloway, Office of Mo. State Auditor, Putnam County Memorial Hospital, Report No. 2017-074 (2017), https://app.auditor.mo.gov/Repository/Press/2017074829206.pdf?_ga=2.205403024.1012106053.1527193832-2129263158.1525706138.

4 *Id.* at 12.

Following the news reporting of the Putnam County Memorial Hospital laboratory billing arrangement, Senator Claire McCaskill called upon the Office of the Inspector General to investigate the arrangement, which only compounded the problems faced by the hospital and its board.[5]

Blue Cross Blue Shield of Missouri sued Hospital Partners, the hospital management company, for $60 million, alleging that the Putnam County Memorial Hospital billing arrangement was a fraudulent billing scheme. The minority shareholders in Hospital Partners sued the majority owners of the company, alleging the defendants put in place an illegal laboratory billing arrangement. The principals in Hospital Partners have been sued by Georgia insurance companies for more than $111 million based on similar billing schemes.[6] The trustees of Putnam County Memorial Hospital have filed litigation against the principals of Hospital Partners, alleging an unauthorized billing scheme to utilize the hospital's billing number.

Although Putnam County Memorial Hospital's doors have remained open, it has been reported that at least eight hospitals managed by the principals of Hospital Partners have filed for bankruptcy protection.[7]

LITIGATION AND BANKRUPTCIES

By 2015 and early 2016, several third party payers noted surges in billing by small rural and community hospitals for laboratory services, particularly toxicology and pharmacogenetic testing services. These payers commenced investigations and audits of the hospital billing, and determined that much of the testing was for non-hospital patients (who were often in different states), the testing lacked adequate documentation of medical necessity, and the hospitals had not performed the testing themselves. Recoupments, lawsuits, and bankruptcies ensued, with third party payers seeking to recoup amounts paid to the hospitals for testing:

1. Chestatee Regional Hospital billed Blue Cross Blue Shield of Georgia for testing performed by Reliance Labs, allegedly representing itself as the performing laboratory. Blue Cross Blue Shield of Georgia sued 14 defendants, including the hospital, its management company, the performing laboratory, and billing

5 Steve Vockrodt, *McCaskill Calls for Federal Probe of $90 Million Billing Scheme at Missouri Hospital*, Kan. City Star (May 28, 2018), https://www.kansascity.com/news/politics-government/article211856169.html.

6 RightChoice Managed Care, Inc. v. Hosp. Partners, Inc., No. 5:18-cv-06037-DGK (W.D. Miss., St. Joseph Div. Jan. 23, 2019).

7 Dan Margolies, *Trustees of Putnam County Hospital Accuse Its Former Owners of 'Overarching Conspiracy,'* NPR (Apr. 16, 2019), https://www.kcur.org/post/trustees-putnam-county-hospital-accuse-its-former-owners-overarching-conspiracy#stream/0.

company. The management company was affiliated with Hospital Partners, discussed above. The hospital closed its doors in July 2018.[8]

2. Another hospital managed by a hospital management company affiliated with Hospital Partners, Campbellton-Graceville Hospital, paid Reliance Labs about $25 million for testing before filing for bankruptcy and closing its doors in June 2017.[9]
3. United Healthcare sued Dr. Michael Murphy, Sun Clinical Laboratories, Sun Ancillary Management, and other related companies for $44 million. The defendants allegedly used financially strapped rural hospitals as "fronts" for billing to conceal the identity of the performing laboratory.[10]
4. Aetna sued People's Choice Hospital, a hospital management company, other related clinical laboratory management companies and laboratories, physicians, and other individuals, alleging a fraudulent scheme to use the hospitals, including Newman Memorial Hospital, for pass-through billing.[11]
5. Blue Cross Blue Shield of Mississippi sued Sharkey-Issequena Community Hospital for billing for more than $30 million of testing that the hospital did not perform.[12]
6. Anthem Blue Cross demanded repayment of at least $13.5 million from Sonoma West Medical Center and its owner, Palm Street Health Care District, claiming that toxicology testing claims were improperly billed to Anthem. From summer 2017 through spring 2018, Sonoma West Medical Center Inc.

---

8 Emma Hurt, *Closing Date Set for Dahlonega's Chestatee Regional Hospital*, WABE (June 28, 2018), https://www.wabe.org/closing-date-set-for-dahlonegas-chestatee-regional-hospital/; Blue Cross & Blue Shield of Ga., Inc. v. DL Inv. Holdings, LLC, No. 1:18-cv-01304 (N.D. Ga. Atlanta Div. Dec. 14, 2018).

9 Jim Axelrod, *How Some Rural Hospitals Were Used to Score Huge Paydays,* CBS News (Mar. 26, 2018), https://www.cbsnews.com/news/how-some-rural-hospitals-were-used-to-score-huge-paydays/.

10 Evan Sweeney, *UnitedHealthcare Accuses Texas Labs of $44M Fraud Scheme*, FierceHealthcare (Apr. 20, 2018), https://www.fiercehealthcare.com/payer/unitedhealthcare-sun-clinical-laboratory-mission-toxicology-fraud; Complaint, UnitedHealthcare Ins. Co., Inc. v. Michael Murphy, M.D. et al., No. 5:18-cv-347 (W.D. Tex. Apr. 18, 2018).

11 Morgan Haefner, *Oklahoma Hospital, Aetna Accuse Management Company of Billing Fraud*, Becker's Hosp. CFO Rep. (Aug. 20, 2018), https://www.beckershospitalreview.com/finance/oklahoma-hospital-aetna-accuse-management-company-of-billing-fraud.html; Complaint, Aetna Inc. v. The People's Choice Hosp., LLC, et al., No. 5:18-cv-00323 (W.D. Texas Sept. 29, 2017).

12 *Blue Cross Says Labs Submitted $33.8M in Bogus Claims*, Law360 (May 5, 2017), https://www.law360.com/articles/920904/blue-cross-says-labs-submitted-33-8m-in-bogus-claims; Complaint, Blue Cross & Blue Shield of Miss. v. Sharkey-Issaquena Cmty. Hosp. et al, No. 3:2017-cv-00338 (S.D. Miss. N. Div. Dec. 13, 2017), https://cases.justia.com/federal/district-courts/mississippi/mssdce/3:2017cv00338/95637/32/0.pdf?ts=1517253438.

generated roughly $30 million in profits from billing for toxicology laboratory services. Approximately $20 million of that total was paid to the laboratory management company.[13]

7. Facing bankruptcy, Little River Healthcare closed its two hospitals stemming from allegations by United Healthcare (claiming $39 million), Aetna (claiming $27 million), and Blue Cross Blue Shield (claiming $26 million) of amounts owed based upon the laboratory billing scheme. An investigate report by Modern Healthcare indicated that one of its hospital's laboratory charges skyrocketed to $213.6 million in 2015 (62% of the hospital's total charges) and to $373.2 million in 2016 (86% of the hospital's total charges).[14]

LEGAL THEORIES

Most of the recoupments and lawsuits that have stemmed from the billing arrangement have been based on the following premises, none of which should be surprising to health care lawyers.

Payers have alleged that the arrangements resulted in the filing of false claims, given that the claims indicated that the hospitals performed the testing and/or that the patients were hospital patients. Federal law and most states prohibit a provider from placing inaccurate or false information on a claim submitted to a third party payer with the intent of securing payment that otherwise would not be available under the payer's policies or guidelines. In *Blue Cross & Blue Shield of Ga., Inc. v. DL Inv. Holdings, LLC*,[15] Blue Cross & Blue Shield of Georgia alleged that Chestatee Regional Hospital and the management company intentionally hid the fact that testing was performed by third party laboratories:

13 E.I. Hillin, *YEAR IN REVIEW: The Hospital Saga Continues,* Sonoma West (Dec. 26, 2018), http://www.sonomawest.com/sonoma_west_times_and_news/news/year-in-review-the-hospital-saga-continues/article_e7f83bf6-093a-11e9-937a-5707f17fd78d.html.

14 Tara Bannow, *Provider with Ties to Lab Billing Scheme May Close*, Modern Healthcare (Dec. 1, 2018), https://www.modernhealthcare.com/article/20181201/NEWS/181209998/provider-with-ties-to-lab-billing-scheme-may-close; Christopher Collins, *Little River Healthcare Shuttered Two Milam County Hospitals After Falling on Hard Financial Times. Now Residents Are Struggling to Find Care*, Tex. Observer (Dec. 14, 2018), https://www.texasobserver.org/how-can-you-do-this-to-people-after-rural-hospitals-close-in-milam-county-residents-scramble-to-find-care/.

15 Complaint, Blue Cross & Blue Shield of Ga., Inc. v. DL Inv. Holdings, LLC, No. 1:18-cv-01304 (N.D. Ga., Atlanta Div. Dec. 14, 2018), https://media.bizj.us/view/img/10844746/anthem.pdf.

> The claims were submitted to BCBS Georgia by Medivance, on behalf of Chestatee, as if testing was performed at and by Chestatee and was reimbursable under the HMO, PAR and PPO Contracts . . . . To facilitate the scheme, Chestatee . . . sought to hide from BCBS Georgia the identity of the laboratory actually performing the testing. Indeed, had Defendants disclosed the entity actually performing the testing (*i.e.*, a non-participating toxicology laboratory such as Reliance Labs), the BCBS Plans would not have paid the claims at issue or would have paid them at substantially lower rates . . . . Defendants, individually and in furtherance of the fraudulent scheme alleged herein, made, or caused to be made, intentional misrepresentations of material facts relating to the claims they submitted or caused to be submitted to BCBS Georgia for reimbursement, with the intent to induce BCBS Georgia to rely on those misrepresentations and pay those claims.[16]

Blue Cross & Blue Shield of Georgia also alleged that the hospital management company tortuously interfered with its contractual agreements with Chestatee Regional Hospital by causing fraudulent claims to be submitted to the payer for reimbursement in breach of the hospital's payer contracts. The complaint alleged that "But for these Defendants' tortious interference with the PAR, HMO, and PPO Contracts, BCBS Georgia would not have paid these claims. The BCBS Plans are entitled to an award of compensatory damages, including consequential damages, together with interest and costs, and an injunction prohibiting Chestatee from continuing to engage in the tortious conduct described above."[17]

The hospitals have faced breach of contract claims, with payers taking the position that their participating provider agreements with the hospitals are intended to cover only services provided to patients of the hospital. The breach of contract claims often included allegations of false claims, as well. For example, in *Blue Cross & Blue Shield of Mississippi v. Sharkey-Issaquena Community Hospital et al.*,[18] Blue Cross & Blue Shield of Mississippi alleged that pursuant to its contract with Sharkey-Issaquena Community Hospital, the hospital was to provide "Hospital Services which are Medically Necessary

16 *Id.* at 38–39 & 65.
17 *Id.* at 79.
18 Complaint, Blue Cross & Blue Shield of Miss. v. Sharkey-Issaquena Cmty. Hosp. et al., No. 3:2017-cv-00338 (S.D. Miss. N. Div. Dec. 13, 2017).

when such services are ordered by a licensed physician or other licensed health care professional who has appropriate staff privileges at [the] Hospital," and the contractual term "Hospital Services" was defined as "those services and supplies provided by [the Hospital] to Subscribers and other patients [and] do not include services performed by an organization or other facility not itself licensed by the state as a general acute hospital."[19] According to the complaint, the claims submitted by Sharkey-Issaquena Community Hospital were not ordered by any physician who had staff privileges at the hospital, nor were the services performed in the hospital's laboratory. In addition, even though third party laboratories performed the testing, the complaint alleged that the claims submitted by the hospital included the hospital laboratory's CLIA number as the performing laboratory. Therefore, the payer took the position that not only did the hospital file claims for payment in breach of the contractual agreement between the parties, the claims also constituted false claims in violation of state law.

In addition to the payer litigation discussed above, minority shareholders of Hospital Partners sued majority shareholders of the hospital management company based on breach of fiduciary responsibility.[20]

As with most lawsuits filed by or threatened by third party payers, the payers in the disputes described above appear to be using litigation as a negotiation tactic to force a settlement. Few small or rural hospitals would have the resources to face a major national or regional third party payer in court.

Several payers have also made allegations that the laboratory billing arrangements–with dollars flowing between the billing hospitals, hospital management companies, performing laboratories, and marketing companies–might violate federal or state kickback laws. It does not appear as though any government enforcement agency has initiated a publicized investigation of the laboratory billing arrangements. This does not mean, however, that such arrangements might not implicate any federal or state kickback laws or that an investigation might not be proceeding quietly. In at least some of the scenarios described above, it appears as though the hospital management companies and/or marketing companies received percentage-based compensation based on revenues from laboratory testing that they arguably were able to "direct" to the laboratories for performance and the hospitals for billing. In addition, the markup in price that the billing hospitals imposed on the laboratory charges, which they

19 *Id.*

20 Dan Margolies, *Mission Hills Couple Sues Over Alleged Lab Billing Scheme at 10 Rural Hospitals*, KCUR (Aug. 13, 2018), https://www.kcur.org/post/mission-hills-couple-sues-over-alleged-lab-billing-scheme-10-rural-hospitals#stream/0.

submitted to third party payers, could raise concerns as a possible kickback from the performing laboratory to the billing hospital. None of these are more traditional kickback arrangements whereby compensation is paid to a referral source by a performing provider because in these scenarios, the billing hospital neither performed nor referred the work. Rather, the laboratory work was typically generated by or on behalf of the performing laboratory. Nevertheless, it is possible that a government enforcement agency could take a broad interpretation of kickback language in the context of these arrangements.

CONCLUSION

Health care lawyers often hear that an otherwise questionable arrangement is acceptable because the arrangement is not specifically prohibited by federal or state laws or regulation and/or because no government payer work is involved. However, the rationales that there is no clear violation of a specific statute or regulation and that no government payers are involved do not insulate clients from significant legal risk. Third party payers have significant contractual and litigation remedies available to them when they believe health care providers have circumvented their contracts and policies. In addition, state attorneys general are taking more aggressive stances regarding the range of conduct that might be implicated by state fraud and abuse and insurance laws, as demonstrated by the investigation of Hospital Partners by the Missouri Attorney General's office.

The reaction of some board members of the Palm Street Healthcare District, the owner of Sonoma West Medical Center (mentioned above) to the laboratory billing scheme is instructive. When told of the arrangement, board members reportedly discussed "a convoluted relationship" involving "questionable" business practices and raised alarms about the moral and ethical basis of a California hospital running a Florida-based toxicology laboratory billing arrangement where almost all of the specimens originated in Florida. One board member bluntly said that the hospital "may be sacrificing [its] integrity here."[21] The lesson here is that if an arrangement appears to put a health care provider's integrity at risk, a thorough and probing analysis of both applicable law as well as the provider's payer contracts should be performed, because there is an increased risk that the arrangement could put more than the provider's integrity at risk. J

21 Robert Michel, *Hospital Board Expressed Doubts About Lab Billing*, XXV Dark Rep. 6 (Mar. 5, 2018), https://www.darkintelligencegroup.com/the-dark-report/laboratory-billing/hospital-board-expressed-doubts-lab-billing/.

Author Profile

JANE PINE WOOD is a licensed and practicing attorney who oversees the BioReference Legal Department, with a focus on legal and regulatory compliance, corporate governance, and corporate ethics. Jane joined BioReference after serving nearly three decades in private practice at McDonald Hopkins LLC. She is a member of the American Health Lawyers Association and has received the Association of Pathology Chairs' Friends of Pathology Award, American Society of Clinical Pathology Patients' Advocate Award, and is listed among Massachusetts Super Lawyers–Top 50 Female Lawyer Award. Jane is a member of the American Bar Association, Massachusetts Bar Association, New Jersey Bar Association, and Ohio Bar. She holds her J.D. from Vanderbilt University School of Law and B.A. in History from Texas A&M University. Contact her via email at jwood@bioreference.com.

American Health Lawyers Association
1620 Eye Street, NW, 6th Floor • Washington, DC 20006-4010
(202) 833-1100 • Fax (202) 833-1105 • www.healthlawyers.org