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.

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