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IN THIS ISSUE

MOB Leases With Unusual Terms Withstand Appraiser Whistleblower Claims

by Sandi Krul and Gary Torrell

On July 31st, the Eleventh Circuit upheld the Southern District of Florida's decision to toss a whistleblower's qui tam claims alleging that HCA violated the False Claims Act. (See *Bingham v. HCA, Inc.*, Case No. 1:13-cv-23671 (11th Cir. 2019)). The Relator, Thomas Bingham, alleged HCA violated the federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b) (AKS) and the federal Stark law, 42 U.S.C. §1395nn(a) (Stark) by entering into what he characterized as sweetheart leasing deals for doctors in medical office buildings at HCA's Centerpoint Medical Center in Independence, Missouri, and Aventura Hospital in Aventura, Florida, in order to induce referrals to HCA. While the leases involved some rather unusual lease terms, including Cash Flow Participation Agreements (CFPA's) that entitled any physician tenant who signed a 10-year lease term to a pro-rata share of the property's operating cash flow (including sale proceeds), the Centerpoint lease was nevertheless determined to be fair market value. The Aventura action was dismissed, so there was no determination respecting fair market value of the Aventura leases.

By way of background, Centerpoint Medical Center was developed through a third party developer that ground leased the property from HCA. The developer then leased out space in the MOB to physicians. The Relator alleged that HCA paid the developer improper subsidies, through an arrangement involving parking facilities at the MOB, and claimed the developer passed these subsidies on to physician tenants through payments under the CFPAs, low initial lease rates, restricted use waivers and free office improvements, to induce physician referrals to HCA. However, independent third party valuations received by HCA concluded that, even when taking account of the CFPAs, parking and other lease terms, the terms were consistent with fair

market value. The Adventura MOB was developed using a similar third party developer structure, including CFPAs with physician tenants, and the Relator alleged HCA provided direct remuneration to referring physician tenants, including free parking and below market rents. The Court found insufficient evidence and upheld summary judgment on the Centerpoint claims in favor of HCA, and dismissed the Adventura claims on procedural grounds.

While the leases involved some rather unusual lease terms the Centerpoint lease was nevertheless determined to be fair market value.

The Centerpoint decision is notable because the Court focused on the Relator's failure to establish improper remuneration under the AKS, by failing to show the leases were not fair market. The court stated that the "value of a benefit can only be quantified by reference to its fair market value." So, notwithstanding that HCA would need to establish fair market value in order to meet the AKS safe harbor, the Relator was first required to establish the leases were not fair market value, in order to establish improper remuneration. Although the lease terms, including the CFPAs, were unusual, the court pointed to the fair market rental range in the valuations, and the valuation conclusions that the rental rates, even when taking into account the terms such as the CFPAs, were within the fair market range established by the valuations at the time the parties entered into the leases. The court also found the Relator failed to provide sufficient facts to support its allegation that HCA made free improvements to certain physician offices and improperly gave certain tenants restricted use waivers.

As for the Stark claim, since the ground lessee developer entered into the MOB space leases with the physician tenants (hence no direct leases between the physicians and HCA), and there was no basis in the record to show that compensation received by the referring physicians varied with or took into account the volume or value of referrals or other business generated by the referring physicians, the leases did not constitute an "indirect compensation arrangement" within the meaning of Stark. The Relator therefore failed to demonstrate any financial relationship between HCA and the physician tenants that violated Stark.

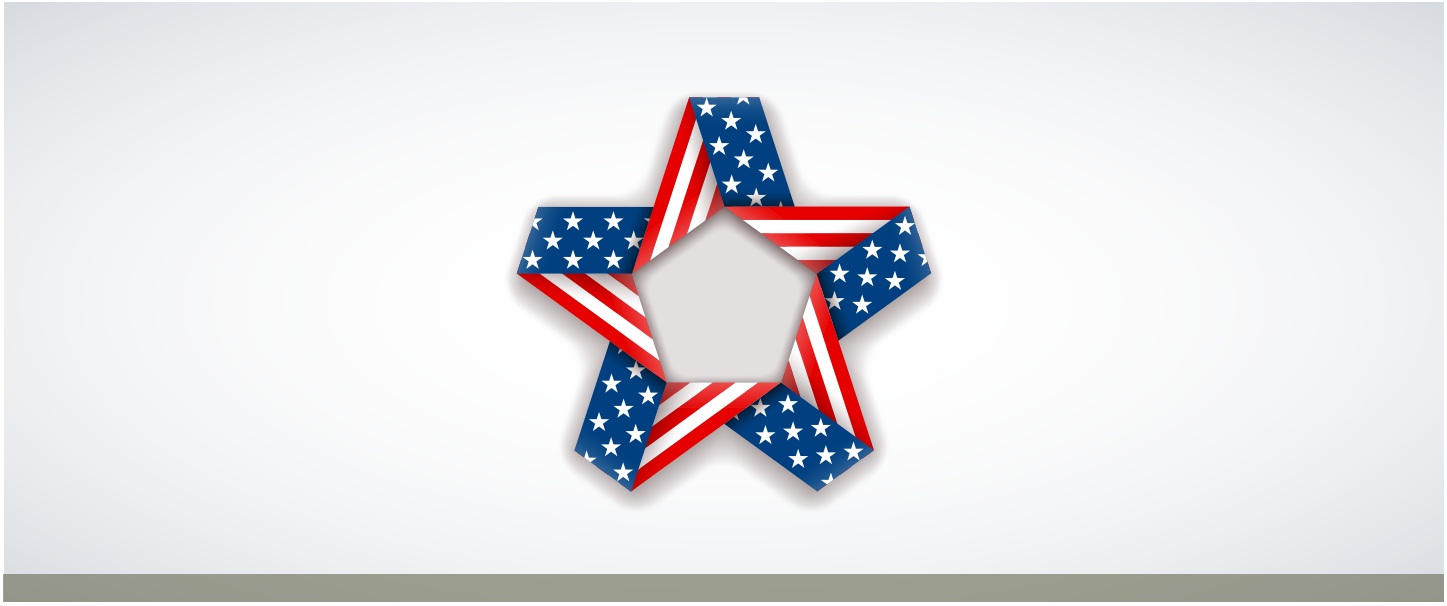
The Centerpoint decision is notable because the Court focused on the Relator's failure to establish improper remuneration under the AKS, by failing to show the leases were not fair market.

One has to wonder whether a different result would have been reached if HCA had not obtained the valuation showing that the benefits of those unusual lease provisions did not tip the scales beyond the fair market range. While valuations are no guaranty against AKS (or Stark) liability, they take on even greater import when entering into leases with such atypical terms.

Although there was no ruling on the merits with respect to the Adventura claims (they were dismissed due to failure to state a claim under the FCA), that decision was also notable in that it reinforced the purpose of the higher pleading standard of Rule 9(b) to ensure that the FCA's strong financial incentives do not "precipitate the filing of frivolous suits" by allowing Relator's to "file suit as a pretext to uncover unknown wrongs." The Relator impermissibly used information learned from discovery to supplement its FCA allegations in order to meet the higher pleading standard of Rule 9(b), and without the additional information the Relator's second amended complaint did not meet that heightened pleading standard and was dismissed.

Finally, it is worth noting that the Relator in this case, Thomas Bingham, was an appraiser with the real estate firm that HCA engaged to provide the valuation, and the same relator in prior suits against health systems alleging similar claims. The case therefore serves as a reminder of the continuing threat of appraiser whistleblowers.
You can find the complete Eleventh Circuit opinion **here**.

If you have questions about this case, healthcare real estate matters, or False Claims Act cases more generally, please contact Pat Hooper, Sandi Krul or Gary Torrell in the Los Angeles office, Ryan Cuthbertson or David Schumacher in the Boston office, Joe LaMagna in the San Diego office, Jordan Kearney in the San Francisco office or your regular Hooper, Lundy & Bookman contact.



VA Expands Veterans' Access To Private-Sector Care

by Paul Garcia

With regulations that became effective on June 6, 2019, the U.S. Department of Veterans Affairs (VA) allows a larger subset of its approximately 9 million enrolled Veterans to seek private-sector medical care outside of traditional VA facilities. This major shift in the VA health care system emanates from the **VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018** ("MISSION Act"), which required the VA to consolidate and expand its existing community care programs into the new Veterans Community Care Program ("VCCP"). The MISSION Act also established a new benefit for veterans to access urgent care outside of VA facilities without prior VA approval.

The VA published separate final rules for the new VCCP and the urgent care benefit on June 5, 2019, with an effective date of June 6, 2019. The VCCP is expected to greatly expand private-sector medical care to veterans. According to the *New York Times*, in fiscal year 2018, 1.7 million veterans used some form of private care. "That number, based on the department's eligibility projections, could increase as much as 30 percent under the new MISSION Act, adding just over a half-million veterans to the pool seeking private care — although both critics and supporters of the change believe that number is low." (**https://www.nytimes.com/2019/06/05/us/politics/va-health-care-veterans.html**)

Private-sector providers interested in rendering care to veterans are encouraged to familiarize themselves with the final rules, which are discussed in more detail below.

VCCP FINAL RULE

Veteran Eligibility

The VCCP final rule establishes when covered veterans may elect to receive services from non-VA entities or providers under the new program.[1] Under the final rule, veterans may elect to receive care from non-VA facilities if they meet one of the following six conditions:

1. The veteran requires care or services that the VA does not provide in any of its facilities (e.g., obstetrics care).
2. The veteran lives in a state where the VA does not operate a full-service medical facility (i.e., Alaska, Hawaii, or New Hampshire) or in a specified U.S. territory.
3. The veteran qualifies under certain "grandfather" provisions related to distances eligibility under the Veterans Choice Program.
4. The VA cannot furnish care within certain designated access standards, including situations where:
    a. The veteran must drive 30 minutes or more to a VA facility for primary care or mental health services, or 60 minutes or more for specialty care.
    b. The veteran cannot receive services within 20-days from the date of request for primary care and mental health care, and 28-days for specialty care.
5. The referring clinician believes that it is in the "best medical interest" of the veteran to receive community care.

[1] 84 FR 26278 (June 5, 2019).

6. The VA has determined that a VA medical service line is not providing care in a manner that complies with the VA's standards for quality based on specific conditions.

    a. In the preamble to the final rule, the VA explains that it is permitted, but not required, to identify underperforming VA medical service lines, and that doing so may not be practically feasible. As such, It may be the case that no covered veterans qualify for community care under this criterion.

With respect to situations where the "best medical interest" provides the basis for a veteran's eligibility, the "best medical interest" standard is met when it is clinically determined that a covered veteran could be expected to experience improved clinical outcomes. The VA stated in the preamble to the final rule that it expects to develop further guidance on this standard, but it does not anticipate reviewing all determinations of the best clinical interests of the veteran.

The sixth condition, which is based on the VA's standards for quality, only applies where the VA identifies an underperforming VA service line, a task that the VA noted may not be practically feasible. As such, it may be the case that no covered veterans will qualify for community care under this condition.

Eligibility decisions are subject to the VA's clinical appeals process, but they are not appealable to the Board of Veterans Appeals. The VA's clinical appeals process is outlined in **VHA Directive 1041, Appeal of VHA Clinical Decisions.**

Provider Eligibility

The final rule does not contain detailed requirements concerning providers' eligibility to furnish care and services under the VCCP; rather, provider requirements will largely be set forth in VCCP contracts with providers. In general, a provider must enter into a contract, agreement or other arrangement to furnish care and services under the VCCP.[2] In addition, the provider must be "accessible" to the covered veteran. The assessment of a provider's accessibility is to include review of the provider's qualifications (e.g., licensing and credentialing information). The VA will also establish access standards for non-VA providers in the contracts, agreements and other arrangements that non-VA providers enter into under the VCCP.

Reimbursement and Claims Adjudication

As a general rule, reimbursement for non-VA providers is based on the Medicare fee schedule. However, rates may be higher in certain rural areas or as determined by the VA based on patient needs, market analysis, health care provider qualifications or other factors.

The MISSION Act includes a section on timely claims submission and prompt payment requirements.[3] These statutory requirements include the following:

- Non-VA providers are to submit claims within 180 days after the date on which the service was provided.
- Paper claims are to be paid within 45 calendar days of receiving a clean paper claim. If the VA denies a paper claim, the VA is to notify the provider regarding reasons for the denial, and request additional information to process the claim.
- Electronic claims are to be paid within 30 days of receiving a clean claim, and if the claim is denied, the VA has 30 days to notify the provider.

For now, it appears that current community providers will not experience immediate changes as a result of the VA MISSION Act of 2018 and the VCCP.[4]

Further, there are no immediate changes to the claims submission process. The VA is to undertake future rulemaking to implement the MISSION Act's prompt payment provisions, as well as additional guidance on billing through the new VCCP.[5] We expect further detail, including payment dispute procedures, to be provided in subsequent guidance.

URGENT CARE FINAL RULE

As part of the MISSION Act, the VA now offers an urgent care benefit that provides eligible veterans with access to urgent care facilities and walk-in retail health clinics without prior approval from the VA.

The VA issued a short final rule outlining the procedures for veterans to access urgent care.[6] Under the final rule, the VA will *only* pay for care under this benefit if the following conditions are met:

1. The veteran is eligible to receive the benefit;
2. The urgent care provider is part of VA's contracted network of community providers; and
3. The services are not excluded under the urgent care benefit (e.g., preventive services and dental services are excluded).

Copayment

A veteran may be charged a VA copayment for urgent care that is different from other VA medical

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[2] See 38 C.F.R. § 17.4030.

[3] 38 U.S.C. § 1703D.

[4] See **https://www.va.gov/COMMUNITYCARE/docs/pubfiles/factsheets/FactSheet_20-13.pdf**

[5] See 84 FR 26278, 26301.

[6] 84 FR 25998 (June 5, 2019).

copayments. Generally the copayment ranges from zero to thirty dollars. The copayments depend on the eligible veteran's priority group, and the number of times they visit an in-network urgent care provider in a calendar year. More detail can be found here: **https://www.va.gov/COMMUNITYCARE/docs/pubfiles/factsheets/VA-FS_Vet-Urgent-Care.pdf**

Community Providers

To reiterate, a provider must be a part of the VA's contracted community care network to provide urgent care to Veterans and be reimbursed by the VA. This means that providers must enter into a contract with one of the VA's Third Party Administrators (TPAs) to be reimbursed for services rendered under this new benefit.

If an otherwise eligible veteran goes to an out-of-network urgent care provider, the veteran may be required to pay the full cost of care, and the VA will not reimburse the provider for the services. There are no exceptions to this requirement.

If you would like more information or need assistance, please contact Paul Garcia in the Los Angeles office, Katrina Pagonis in the San Francisco office, or your regular Hooper, Lundy & Bookman contact.

Proposed Payment Models Aim to Incentivize Changes in Care Delivery for Chronic Kidney Disease and ESRD Patients

by Amy Joseph, Ryan Cuthbertson

On July 10, 2019, the President issued the **Executive Order on Advancing American Kidney Health**, and the U.S. Department of Health & Human Services released a corresponding **Proposed Rule and various related materials** announcing proposed payment models to incentivize changes in radiation oncology (RO) and treatment of chronic kidney disease (CKD) and end stage renal disease (ESRD). This article focuses on the proposed CKD and ESRD payment models. In particular, HHS announced five proposed payment models, one of which is mandatory and will impact approximately half of the country, and all of which are proposed to commence potentially as soon as January 1, 2020. Among other things, the models focus on incentivizing better care for those with chronic kidney disease, home dialysis and kidney transplantation as alternatives to in-center hemodialysis, as a means to achieving lower cost, higher quality of care for beneficiaries. A high level summary of these five models follows.

Comments to the Proposed Rule (which addresses the mandatory payment model) are due by September 16, 2019, and given the significant change to reimbursement methodology and number of related open questions, stakeholders would be well advised to weigh in.

PROPOSED MANDATORY MODEL – ESRD TREATMENT CHOICES (ETC) MODEL

The ETC Model seeks to encourage greater use of home dialysis and kidney transplant for Medicare beneficiaries with ESRD, by: (1) adjusting the ESRD Monthly Capitation Payment (MCP) for nephrologists and other clinicians that manage the care of such beneficiaries (Managing Clinicians); and (2) adjusting the ESRD Prospective Payment System's per treatment base rate for ESRD facilities.

A large number of providers that provide care for ESRD patients will be affected, and assuming the timeline remains on track, there is little time before the payment model commences. Managing Clinicians and ESRD facilities would be selected from a random sample of 50% of the 306 Dartmouth Atlas Project's Hospital Referral Regions (HRRs), with the goal of accounting for the care of approximately 50 percent of adult ESRD beneficiaries. Proposed payment adjustments would apply to claims with dates ranging from January 1, 2020 through June 30, 2026.

The ETC Model includes a potential positive additional payment adjustment for claims for home dialysis and related services by both Managing Clinicians and ESRD facilities through a Home Dialysis Patient Adjustment (HDPA) during the first 3 years of the model, with the adjustment percentage declining annually (from 3% to 1%).

Separately, a Performance Payment Adjustment (PPA) with two-sided risk applies to both Managing Clinicians and ESRD facilities for the entire duration of the model, with increasing levels of positive or negative adjustment over the course of the time period. Beneficiaries would be attributed to Managing Clinicians and ESRD facilities on a monthly basis, based on where they receive most of their dialysis treatments and the clinician who submits the monthly capitation payment claim for the month. Some categories of beneficiaries are excluded, including, without limitation, beneficiaries enrolled in a Medicare Advantage plan, beneficiaries under age 18, and beneficiaries that have elected hospice. Of particular note, CMS considered, but did not include, age or housing insecurity as factors for excluding beneficiaries from the model, given lack of consensus regarding the appropriate age cut-off or objective measures for housing insecurities. After attribution of beneficiaries to ESRD facilities and Managing Clinicians, a performance assessment of home dialysis and transplant rates is conducted, and risk and reliability adjustments are also applied. Then, a methodology is applied to measure "achievement scoring" (comparing participants' home dialysis and transplant rates against benchmarks for non-participants) and "improvement scoring" (comparing participants' home dialysis and transplant rates to their respective historical rates). A "Modality Performance Score" is calculated based on the achievement and improvement scores for home dialysis and transplants, and that score determines the level of positive or negative payment adjustment. For ESRD facilities, the payment adjustment can range from -8.0% to +5.0% in the first adjustment period, and that range nearly doubles by the end of the proposed payment model. A similar percentage range applies for Managing Clinicians.

> Among other things, the models focus on incentivizing better care for those with chronic kidney disease, home dialysis and kidney transplantation as alternatives to in-center hemodialysis

Additional requirements would apply, including notification to beneficiaries if a clinician or facility is participating in the payment model.

VOLUNTARY PAYMENT MODELS – KIDNEY CARE FIRST (KCF) AND COMPREHENSIVE KIDNEY CARE CONTRACTING (CKCC) MODELS

The KCF Model and three CKCC Models were also announced as new voluntary payment models on July 10, however very few specifics have been provided yet regarding eligibility, requirements, and payment methodology. Both the KCF and CKCC models are intended to incentivize better management of kidney disease, by making a single set of providers responsible for an aligned patient's kidney care throughout the entire treatment lifecycle (late stage chronic kidney disease through dialysis and post-transplant care). CMS states that the models build on lessons learned from the Comprehensive ESRD Care (CEC) model and recently launched Direct Contracting Models.

These models will run from January 1, 2020 through December 31, 2023, with the option to extend for additional payment years at CMS's discretion. Providers must apply to participate in the fall of 2019 (i.e., just a few months away). However, 2020 (otherwise known as "year 0" will not entail financial accountability, but will be focused on "standing up" the models. Financial accountability would commence in 2021. Key goals include delay of disease progression, management of transition to dialysis, and supporting beneficiaries through the transplant process, with an emphasis on patient education and active involvement in decision making for their care.

The KCF model will be open to nephrology practices and

nephrologists only. Participating nephrologists and nephrology practices will receive adjusted capitated payments for managing care of aligned beneficiaries with CKD Stages 4 or 5 and those on dialysis, based on health outcomes, utilization, and quality measures. Notably, KCF practices will also receive a bonus payment for each beneficiary that receives a kidney transplant, payable in increments over three years after the transplant (if the transplant remains successful).

The 3 CKCC models – the Graduated Model, Professional Model, and Global Model – will be open to Kidney Contracting Entities (KCEs). KCEs must each include nephrologists and transplant providers as participants, while dialysis facilities and other providers and suppliers are optional participants. The Graduated Model has a one-sided risk track, akin to the current CEC one-sided model, allowing certain participants to incrementally phase in to greater potential risk and reward. The Professional Model is a two-sided risk model, with a potential of up to 50% of shared savings or liability of up to 50% of shared losses based on total cost of care for Part A and B services for the aligned beneficiary. Under the Global Model, KCEs take on 100% risk for total cost of care for Part A and B services.

These models have a similar flavor to the new tracks for Medicare Shared Savings Program (MSSP) ACOs under the Pathways to Success final rule, emphasizing greater shared risk and reward for management of beneficiary care. In addition, similar to MSSP ACOs under the Pathways to Success final rule, additional flexibility is provided for telehealth services in non-rural locations, waiver of the 3-day skilled nursing facility rule, and provision of additional home visits and home health services post-discharge and for care management.

UNCERTAINTY IN ADVANCE OF COMMENCEMENT DATE

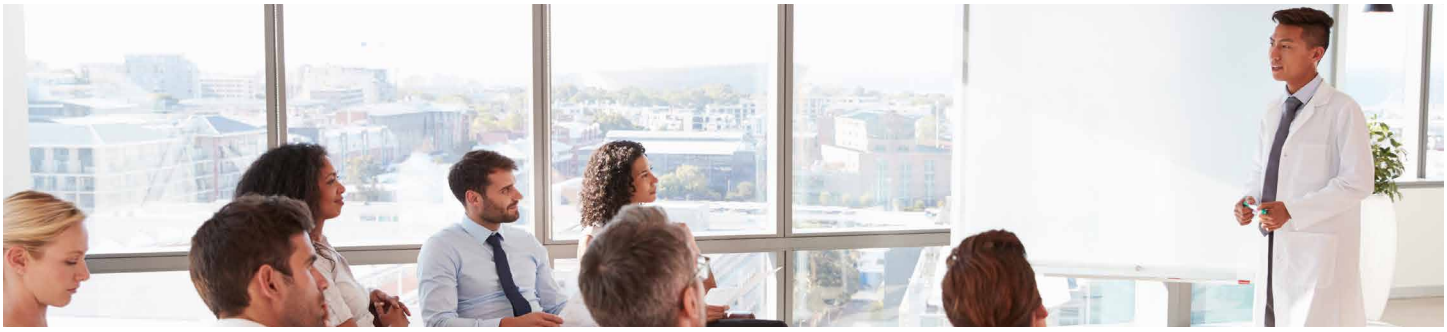
Many questions remain in advance of the commencement date of January 1, 2020, including which geographic regions will be required to participate in the model. CMS has specifically asked for comments in the mandatory model proposed rule on a number of aspects of the ETC model (the mandatory payment model), including, without limitation:

- Whether the start date of January 1, 2020 should be pushed to April 1, 2020;
- Required content in materials provided to beneficiaries with respect to the models;
- The look-back period for CMS's "right to correct" a prior incorrect payment for participation in the model;
- Timing of notice requirement for name changes (note that ETC Model participants would also be required to provide notice at least 90 days in advance of a change in control, which is a significant departure from current post-close filing requirements for transactions, along with immediate reconciliation of any funds owed to CMS);
- Selection process for participants;
- Whether the payment adjustments should apply when Medicare is the secondary payer; and
- Amount of payment adjustments and associated methodology to calculate adjustments.

In addition, because there is not much detail available yet with respect to the voluntary KCF and CKCC payment models, providers will need to be prepared to review and make decisions quickly this fall regarding whether to apply to participate in such programs, once additional information is released along with the Request for Applications (RFA).

September 16, 2019	Submission deadline for comments to Proposed Rule
Fall 2019	Request for Applications for KCF and CKCC models expected
January 1, 2020	Start date for ETC, KCF and CKCC models (ETC model start date may be pushed back to April 1, 2020)
December 31, 2023	KCF and CKCC models end, unless extended by CMS
June 30, 2026	ETC model ends (end date may be delayed to correspond with potential delayed start date)

If you would like more information, please contact Amy Joseph or Ryan Cuthbertson in the Boston office, Karl Schmitz in the Los Angeles office, or Kelly Carroll, Marty Corry, Alex Brill, Kelly Delmore or Monica Massaro in the Washington, DC office or your regular Hooper, Lundy & Bookman contact.



A Quick Briefing of State Approaches to Surprise Billing

by Ryan Cuthbertson

In June, my colleagues Kelly Delmore and Katrina Pagonis provided an update on the various approaches to surprise billing being considered on the Hill. We are continuing to follow that process closely, but federal legislation is currently on hold during the congressional summer recess. This creates an opportunity for an evaluation of developments in surprise billing laws at the state level.

Balance billing, often referred to as "surprise billing," occurs when an out-of-network provider bills a patient for the difference between the provider's charges and the amount the provider received from the insurer. Sometimes, a patient understands that he or she will be responsible for the balance and chooses to see an out-of-network provider anyway. Often, however, balance billing results from situations where a patient did not have the opportunity to choose his or her provider because the services were furnished (1) in an emergency situation, (2) by an out-of-network professional in an in-network facility, or (3) by an out-of-network diagnostic imaging or laboratory provider in connection with an in-network service.

Despite the recent focus on surprise billing at the federal level, patients have been dealing with these issues for many years, and several states have had surprise billing laws in place for some time (or have strengthened their existing laws in recent years). Others are just now starting to join the fray. Although some states have fairly comprehensive regulatory frameworks for patients covered by state-regulated insurance, ERISA preemption precludes states from addressing self-funded, employee-sponsored health plans' coverage of out-of-network care. Thus, this article sets forth a few examples of how certain bellwether states are attempting to address surprise billing. These summaries are intended to provide a high-level look at the components of the laws and do not address more nuanced regulatory details.

NEW YORK

For non-emergency services, the protections apply if the patient receives services from an out-of-network provider at an in-network hospital or ASC, and (a) an in-network provider was not available, (b) an out-of-network provider provided services without the patient's knowledge, or (c) unforeseen medical circumstances arose at the time the services were provided. In the event that a patient is referred by an in-network provider to an out-of-network provider, the protections will apply if the patient did not sign a written consent that the patient knew the services would be out-of-network and would result in costs not covered by the insurer. Insured patients are only responsible

for in-network co-sharing amounts if they sign an Assignment of Benefits form and send it to the insurer along with the surprise bill. Insurers (other than self-funded plans) must also hold patients harmless for emergency services costs beyond the in-network co-sharing amounts. Additionally, patients do not have to pay out-of-network providers for emergency services beyond their in-network co-payment, co-insurance, and deductible amounts.

Reclassification of these costs to the Administrative & General cost center may mean that a hospital will receive no payment for the costs of its allied health programs.

The law implements disclosure requirements to ensure that a patient is made aware of the potential implications of receiving out-of-network services. Providers, practices, and certain health facilities must provide the names of health plans in which they participate and any affiliated hospitals, as well as estimated cost information. Physicians must also provide the names and contact information of any other providers that will be providing services to the patient to allow them to determine whether such providers are in-network.

For patients that sign the Assignment of Benefits form, the provider must look to the insurer for reimbursement. If a provider disputes the payment amount, it may submit the dispute through an independent dispute resolution process administered by the Department of Financial Services. In a process typically called "baseball-style arbitration," the independent dispute resolution entity makes a determination within 30 days and chooses to enforce either the provider's billed amount or the insurer's payment amount based on certain enumerated factors. It may also direct the parties to further negotiate in good faith. Additionally, the party whose fee was not chosen pays the costs of the dispute resolution process, unless the parties are able to settle the dispute, in which case the costs are shared. Lastly, uninsured patients, patients that do not sign the Assignment of Benefits form, and those with self-funded plan coverage may submit disputes through the process if they did not receive the required disclosures.

CALIFORNIA

For emergency services, the insurer must pay the out-of-network provider the "reasonable and customary value for the health care services rendered based upon statistically credible information that is updated at least annually." Balance billing an enrollee for emergency or certain post-stabilization services is considered an unfair billing practice. The surprise billing rules for emergency and post-stabilization services, however, only apply to patients enrolled in coverage with an HMO or other payor regulated by the Department of Managed Health Care. Individuals insured by plans regulated by the Department of Insurance, however, are not protected.

For non-emergency services that a patient receives at an in-network facility (from an out-of-network provider), the patient is only responsible for the in-network cost-sharing amount. The insurer must pay the out-of-network provider the greater of (a) the insurer's average contracted rate paid for similar services in the region, or (b) 125% of the Medicare fee-for-service reimbursement rate. This rule applies whether the patient is enrolled in a plan regulated by the Department of Managed Health Care or the Department of Insurance.

There is an independent dispute resolution process implemented by the Department of Insurance if the out-of-network provider contests the payment amount for out-of-network, non-emergency services at a network facility. HMOs and other plans regulated by the Department of Managed Care must make an internal dispute resolution mechanism available to out-of-network providers.

CONNECTICUT

Insureds in Connecticut that receive out-of-network emergency services or non-emergency services from an out-of-network provider in an in-network facility are only responsible for the co-payment, coinsurance, and deductible amounts that they would have incurred for in-network services.

For emergency services, the patient's insurer must pay the out-of-network provider the greater of (a) the amount that the insurer would have paid an in-network provider; (b) the usual, customary, and reasonable rate for the services; or (c) the amount that Medicare would pay for the services. This is similar to the federal rule adopted under the Affordable Care Act at 45 CFR § 147.138(b). For non-emergency services, the insurer must reimburse the out-of-network provider the amount it would have paid an in-network provider and the provider must accept this amount as payment in full.

Connecticut also imposed certain disclosure obligations on insurers to provide enrollees with accurate provider network status information and estimates of the amounts insurance will pay. Online participant provider directories must be maintained and updated every month.

ILLINOIS

For emergency services, insurers must provide coverage that is not dependent on whether the services were provided on an in-network or out-of-network basis. In addition, patients are only responsible for in-network cost-sharing amounts for out-of-network

radiology, anesthesiology, pathology, emergency physician, or neonatology services when (a) the patient goes to an in-network hospital or ASC and (b) an in-network radiologist, anesthesiologist, pathologist, emergency physician, or neonatologist was unavailable. The patient is also required to assign his or her benefits to the out-of-network provider, and the insurer must reimburse the provider directly.

Out-of-network providers may initiate arbitration proceedings if a payment dispute with an insurer is not settled within 30 days.

Insurers have certain contractual disclosure requirements, such as defining surprise bills in the coverage descriptions, providing cost estimates for services to enrollees, and providing a way for enrollees to determine the network status of providers. Providers are also required to make a good faith effort to tell patients whether they have a contract with the patient's insurer.

ARIZONA

A patient may request a mediation of a balance bill from an out-of-network provider for services furnished in an in-network facility if (a) the bill is over $1,000, (b) the patient did not know that the provider was not an in-network provider, (c) an in-network provider was not available or it was impractical to wait for the in-network provider, and (d) the patient did not elect to obtain an out-of-network service. The new law does not separately distinguish emergency situations.

WASHINGTON

Washington's surprise billing statute just became effective at the end of July. The new law prohibits an out-of-network provider or facility from balance billing a patient for (a) emergency services or (b) non-emergency out-of-network services provided at an in-network hospital or ASC and involving surgical or ancillary services. Until federal legislation or an interstate compact prohibits balance billing for emergency services, the insurer must hold the patient harmless from balance billing when the emergency services are provided by an out-of-network hospital that borders Washington State. The provider may collect no more than in-network cost-sharing amounts payable under the patient's plan from the patient.

Similar to Connecticut, an out-of-network provider may initiate arbitration if it cannot settle the dispute within 30 days, and the new law provides a number of procedural requirements for the arbitration process. Lastly, there are a number of provider and plan disclosure requirements. For example, providers and insurers must provide network affiliation information on their websites, and providers and plans must give patients certain information about their rights under the new surprise billing law.

COLORADO

Colorado's surprise billing law was enacted in May of this year that will largely take effect on January 1, 2020. Under this law, patients who receive emergency services at out-of-network facilities or non-emergency services at in-network facilities from out-of-network providers are only responsible for applicable in-network cost-sharing amounts. The provider must submit the out-of-network claim for reimbursement to the insurer within 180 days, and the insurer must pay based on the following statutory formula: (a) for emergency services, the insurer must pay the greater of (i) 110% of the median in-network rate, or (ii) the 60th percentile of the in-network rate for the prior year based on a state claims data, and (b) for non-emergency services, the insurer must pay the greater of (i) 105% of the median in-network rate, or (ii) the median in-network rate for the prior year based on data. The law also imposes disclosure requirements on healthcare facilities, providers, and insurers to inform patients of the effects of obtaining non-emergency services from out-of-network providers or facilities, and it imposes certain data reporting requirements for the Department of Insurance to track. Lastly, the law establishes a mandatory, binding arbitration process for out-of-network provider-payor disputes that are not settled during an optional 30-day negotiation period.

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The foregoing examples provide a window into some of the state-law approaches that have been adopted by the 60% or so of states that have addressed surprise billing for out-of-network emergency services and/or for non-emergency out-of-network services furnished in in-network facilities. State legislation around surprise billing has generally been gaining traction over the past several years. This trend is likely to continue now that surprise billing is a national legislative priority because the federal focus on the issue generally increases attention to surprise billing issues and because any exception from preemption included in federal legislation for states that regulate surprise billing will create an incentive for states to legislate. We will continue to monitor congressional efforts around surprise billing in the coming months, including the complex potential interactions between any federal bills and existing state laws on surprise billing.

If you would like more information or need assistance, please contact Ryan Cuthbertson in the Boston office, Katrina Pagonis in the San Francisco office, Kelly Delmore in the Washington, D.C. office or your regular Hooper, Lundy & Bookman contact.

CMS Proposes Significant and Far-Reaching Hospital Price Transparency Requirements in CY 2020 OPPS Proposed Rule

by Katrina Pagonis, Eric Chan, Kelly Carroll, Alicia Macklin, Sansan Lin, and Monica Massaro

On Monday, July 29, 2019, the Centers for Medicare & Medicaid Services (CMS) released the 2020 Outpatient Prospective Payment System (OPPS) Proposed Rule (the Proposed Rule). In it, CMS proposes an anticipated but extraordinarily burdensome price transparency rule that would require hospitals to publicly disclose negotiated prices with third party payers in connection with their disclosure of "standard charges" under section 2718(e) of the Public Health Services Act.

The Proposed Rule also contains notable proposals concerning supervision of therapeutic services in hospital outpatient departments; prior authorization requirements for a limited set of outpatient procedures; continuation of the 340B price reduction; implementation of the second phase of site-neutral payment for clinic visits at off-campus, provider-based departments; and the certification of organ procurement organizations.

PRICE TRANSPARENCY

CMS describes the Proposed Rule as "bold action . . . to empower patients with price transparency," and the Proposed Rule certainly includes significant and far-reaching proposals to advance the Administration's goal of furthering price transparency in healthcare. The Administration has made price transparency a priority this year, as underscored by President Trump's June 24, 2019 Executive Order on the topic. Although the statute only requires "a list" of "standard charges," the proposed rule would require hospitals to include negotiated rates with third party payers alongside its charges in two publicly available files—a machine-readable file with charges for all items and services and a consumer friendly list that focuses on 300 "shoppable services."

- **Statutory Background and Current Requirements.** Under section 2718(e) of the Public Health Services Act, all hospitals are required to "establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups." Based on 2014 guidance, hospitals could comply with the statute by "either mak[ing] public a list of their standard charges, or their policies for allowing the public to view a list of those charges in response to an inquiry." Under guid-

ance released last year, however, hospitals are currently required to make their chargemasters public in machine-readable format, which should include all items and services (including drugs) provided by the hospital as well as diagnosis-related group information (e.g., data in the Inpatient Utilization and Payment Public Use File). CMS indicated that future rulemaking would address "[s]pecific additional future enforcement."

- **The Price Transparency Executive Order.** CMS' proposals follow from President Trump's direction in a June 24, 2019 executive order (EO) to increase health care price and quality transparency. The EO's stated goal was to help patients "know the price and quality of a good or service in advance of [receiving] care." The EO directs the Department of Health and Human Services ("HHS") and other agencies to issue rules, guidance, or reports, including rules requiring "hospital[s] to publicly post standard charge information, including charges and information based on negotiated rates and for common or shoppable items and services, in an easy-to-understand, consumer-friendly, and machine-readable format." The EO also requires advance notice of proposed rulemaking to obtain comments on how providers, insurers, and self-insured group health plans could be required to share anticipated out-of-pocket cost information with patients and a report on barriers to price and quality transparency resulting from federal government and private sector actions, and proposals to eliminate such barriers and increase competition.

> CMS proposes an anticipated but extraordinarily burdensome price transparency rule that would require hospitals to publicly disclose negotiated prices with third party payers

- **"Payer-Specific Negotiated Charges."** Under the Proposed Rule, payer-specific negotiated charges would mean "the charge that a hospital has negotiated with a third party payer for an item or service." Although the Proposed Rule uses the term "charges," it is referencing the rates negotiated between hospitals and third party payers. This data would need to be included in both the machine-readable file of all items and services provided by the hospital, as well as in the consumer-friendly list of at least 300 shoppable services.

- **"Shoppable Services."** CMS proposes a list of 70 "shoppable" services that would be required to be included in the consumer-friendly list of "standard charges." These include various evaluation and management services, laboratory and pathology services, radiology services, and medicine and surgery services. In addition, providers would be required to include additional "shoppable" services for a total of 300 items for inclusion on the consumer-friendly list.

- **Civil Monetary Penalties**. The proposed rule would permit CMS to initiate enforcement actions and to impose civil monetary penalties (CMPs) of up to a maximum of $300 a day where a provider fails to comply with the price transparency regulations. The CMP would generally follow a written warning and the failure to either submit or comply with a corrective action plan. CMS is also proposing to publicize each notice of imposition of a CMP online, even while such CMP is being appealed, only removing the public notice if the CMP is overturned by a final and binding decision. CMS is requesting comments on imposing stronger penalties or limiting the maximum amount of a penalty, as well as the unintended consequence of the proposed penalties and whether other penalties should be applied.

The foregoing price transparency proposals raise a number of significant legal and practical problems, some of which are summarized below:

- Limits of Statutory Authority. These proposals may exceed CMS' statutory authority under Section 2718(e) of the Public Health Service Act, which only speaks to public disclosure of "standard charges" rather than competitively negotiated rates. CMS may also lack authority to promulgate rules relating to the enforcement of the new price transparency rules. CMS relies upon Public Health Services Act section 2718(b)(3), which contains ACA's provisions relating to the medical loss ratio and rebate requirements that ACA imposed upon health insurers. It does not address enforcement of the requirement to disclose standard charges pursuant to Section 2718(e).

- Impact on Competition. The disclosure of negotiated discounts from a hospital's charges are likely to have significant, adverse impacts on competition. Such discounts are widely recognized to be competitively sensitive by providers and payers alike. CMS admits "the impact resulting from the release of negotiated rates is largely unknown" and that doing so "may have the unintended consequence of increasing health care costs" and/or encouraging "anticompetitive behaviors"—along the lines of the oft-discussed "Danish cement" case study. (See Section XVI.D.2. of the Proposed Rule) The Proposed Rule does not indicate any consultation with the Antitrust Division of the Department of Justice or the Federal Trade Commission.

- Operational Difficulties. The Proposed Rule appears to un-

derestimate the amount of data to be disclosed and the amount of work involved for hospitals. Notably, CMS assumes that "it presents little burden for a hospital to electronically pull and display" negotiated rates for individual payers. But data about negotiated rates for individual payers may or may not be stored in a hospital's billing software in a format that can be readily extracted. Such rates are not "routinely used for billing," as CMS contends. Rather, bills submitted by a hospital typically list the hospital's gross charges for services provided, and the payer determines payment during the claim adjudication process. CMS further assumes that the charge for each item or service on a hospital's chargemaster can be readily tied to a dollar amount by the hospital and that hospitals and consumers will be able to map between individual items and services and the various configurations of "service packages" (e.g., per diem stays, diagnosis-related groups) used by different payers.

- Disconnect with Trends in Managed Care. Over the past decade, managed care has continued to move toward shared-risk arrangements and value-based payments. The Proposed Rule does not acknowledge or address how providers that receive capitation payments, bundled care payments, shared savings or shared risk pool distributions, or quality incentive bonuses could comply with the regulations. It is possible that such arrangements are excluded from the proposed definition of "standard charge" ("the regular rate established by the hospital for an item or service provided to a specific group of paying patients"), but it is puzzling that there is no discussion of the consumer confusion that might result or the other impacts of the exclusion of these types of arrangements.

- Identifying the Payer. CMS also assumes that the third party payer can be identified in every instance, and that each discount is "payer-specific." This is not true where, for example, the hospital has signed a "rental" or "network access" agreement and may not know the identities of all the payers who may "access" such an agreement.

These price transparency proposals will almost certainly prompt significant public comment. For now, serious questions remain about whether Public Health Services Act section 2718(e) gives CMS sufficient authority to promulgate these rules; whether the agency has or can sufficiently address trade secret and antitrust considerations; whether it is even operationally feasible to comply with the Proposed Rule; and, even if so, whether much of this information is more efficiently obtained from payers than from hospitals.

OTHER ISSUES OF NOTE

Prior Authorization Process Proposal. CMS proposes for the first time in the fee-for-service context a prior authorization process for five categories of hospital outpatient department services: (1) blepharoplasty, (2) botulism toxin injections, (3) panniculectomy, (4) rhinoplasty and (5) vein ablation. This prior authorization proposal stems from CMS' stated goals of managing the growth of Medicare spending for outpatient department services, and CMS claims that the prior authorization requirement is permissible as "a method for controlling unnecessary increases in the volume" of covered outpatient department services under 42 U.S.C. § 1395l(t)(2)(F). CMS indicates that volume increases for these services were higher than expected and notes that the specified services are likely to be cosmetic surgical procedures and/or are directly related to cosmetic procedures that are not medically necessary.

CMS proposes that as a condition of Medicare payment for services that fall within the five specified categories, a provider must submit a prior authorization request that includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. This request must be submitted before the service is furnished to the beneficiary and before the claim is submitted. The Proposed Rule sets a ten or two business day deadline (depending on the severity that any delay would have on the beneficiary) as the deadline for CMS or its contractor to review and issue a decision on authorization requests. The Proposed Rule also gives CMS the option of exempting a provider from the prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding and payment rules. Any such exemption would remain in effect until CMS withdraws it.

Level of Supervision. CMS is proposing to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by hospitals and critical access hospitals (CAHs). General supervision means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. This proposal is motivated by CMS' desire for a uniform enforceable supervision standard for all hospital outpatient therapeutic services,[1] as well as by CMS' recognition that the direct supervision requirement for hospital outpatient therapeutic services places an additional burden on providers. CMS also notes that, in its experience, Medicare providers will provide a similar quality of services, regardless of the supervision required. CMS is seeking public comments on this proposal, as well as specific comments on whether there are any types of services that should be excepted from the proposal.

340B Drug Payment and Litigation. CMS proposes to continue to pay ASP minus 22.5 percent for 340B-acquired

drugs, as it has since CY 2018, when the rate was reduced from ASP plus 6 percent to ASP minus 22.5 percent. In the Proposed Rule, CMS acknowledges the federal district court rulings in American Hospital Association. v. Azar, No. 18-cv-2084 (D.D.C.), within the last year, wherein the court concluded that the Secretary exceeded his statutory authority when imposing those rate reductions for 340B-acquired drugs in CY 2018 and CY 2019. While the Secretary has appealed the case to the D.C. Circuit, in this Proposed Rule, CMS seeks public comments as it takes steps to craft a remedy in the event of an adverse decision for the agency on appeal. CMS states that in the event of such an adverse appellate decision, it anticipates proposing the specific remedy for CYs 2018 and 2019, and, if necessary, changes to the CY 2020 rates, in the next available rulemaking vehicle, which is the CY 2021 OPPS proposed rule. Those proposals will be informed by the comments solicited in this Proposed Rule.

CMS first seeks comments on the appropriate OPPS payment rate for 340B-acquired drugs, including whether a rate of ASP plus 3 percent could be an appropriate payment amount for 340B-acquired drugs, both for CY 2020 and for purposes of determining the remedy for CYs 2018 and 2019. CMS also is soliciting comments on how to structure the remedy for CYs 2018 and 2019. More specifically, CMS seeks comments on: (1) whether such a remedy should be retrospective in nature (for example, made on a claim-by-claim basis), (2) whether such a remedy could be prospective in nature (for example, an upward adjustment to 340B claims in the future to account for any underpayments in the past), and (3) whether there is some other mechanism that could produce a result equitable to hospitals that do not acquire drugs through the 340B program while respecting what CMS describes as a "budget neutrality mandate." Finally, CMS asks for comments on the most appropriate treatment of beneficiary cost-sharing responsibilities under any proposed remedy.

> CMS is proposing to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services

Organ Procurement Organizations Changes and Request for Information. The Proposed Rule revises the Organ Procurement Organization (OPO) Conditions for Certification (CfC) as a step toward the Administration's Advance Kidney Health Initiative launched from President Trump's recent Executive Order to increase utilization of available organs. Currently, OPOs are required to meet two of three outcome measures. The Proposed Rule revises the definition of "expected donation rate" that is included in the second outcome measure to make it consistent with the definition used by the Scientific Registry of Transplant Recipients (SRTR)—a definition that was adopted in 2009. The revision would define the expected donation rate per 100 eligible deaths as "the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations."

The Proposed Rule also includes a Request for Information regarding the OPO CfCs and the Conditions of Participation (CoPs) for transplant centers that must be met for payment. The RFI seeks comments in six areas covering the impacts, consequences and reliability of OPO outcomes measures. The Proposed Rule also solicits public comments on two potential OPO outcome measures: (1) the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation; and (2) the actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. Lastly, in addition to the public comments of these two listed outcome measures, CMS is also interested in public comments on the appropriate parameters for these measures. CMS indicates it will use this feedback in a comprehensive proposal in future rulemaking expected later this year.

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The foregoing is a sampling of key highlights found among the more than 819 pages of the Proposed Rule. Comments on CMS' proposals are due on September 27, 2019. The Proposed Rule will be published in the Federal Register on August 9, 2019 at **https://federalregister.gov/d/2019-16107**. In the interim, the unpublished version is available at **https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-16107.pdf.**

For more information on the OPPS and price transparency, please contact, Katrina Pagonis in the San Francisco office, Eric Chan, Alicia Macklin or Sansan Lin in the Los Angeles office, or Kelly Carroll, Marty Corry, Kelly Delmore or Monica Massaro in the Washington, DC office or your regular Hooper, Lundy & Bookman contact.

[1] Since approximately 2010, CMS has instructed all MACs not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs or small rural hospitals having 100 or fewer beds. These enforcement instructions created a two-tiered system of supervision requirements for hospital outpatient therapeutic services for providers in the Medicare program: for most hospital outpatient therapeutic services in most hospital providers, direct supervision is required, but for most hospital outpatient therapeutic services in CAHs and small rural hospitals with fewer than 100 beds, only general supervision is required.

LAWYER Q+A

Gary Torrell

Gary Torrell is a partner in HLB's Business Department. He has over 30 years of legal and business experience with a focus on business and finance, real estate, and creditors' rights. Gary combines efficiency with sophisticated advice and services to provide exceptional value. He is both a transactional and litigation lawyer, and a court-approved mediator, which helps his clients feel protected and prepared for virtually any circumstance.

Gary also brings vast bankruptcy expertise to HLB and represents clients in bankruptcy courts and appellate courts across the country, including heath care providers. Examples include when a tenant or landlord of a heath care provider files bankruptcy; a provider's major supplier/vendor files bankruptcy; a medical group with whom the provider does business files bankruptcy; providers which make secured and unsecured loans and the doctor or medical group (borrower) file bankruptcy; providers which seek to acquire health care assets-including entire hospitals and medical office buildings, when the seller is in bankruptcy or is about to file bankruptcy; and when providers are sued to recover money received in the months leading up to the bankruptcy for goods and services from the provider-commonly called lawsuits to recover preferential transfers or fraudulent conveyances.

How has your practice evolved in the last 5 years?

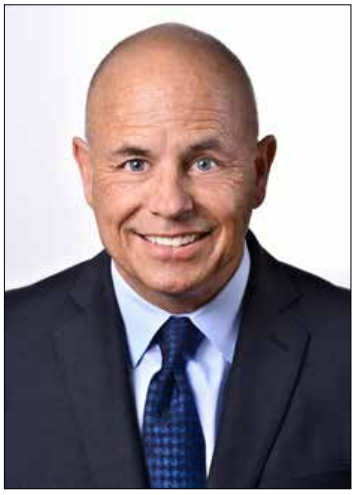
My practice has become increasingly focused on the healthcare industry, culminating in a client's purchase of a two-facility SNF in late 2018 and a much larger, two facility hospital/MOB complex in March 2019. Plus, healthcare clients and other clients have asked me to do more kinds of legal work and provide business advice.

What hot issues are your health care clients facing?

Increasing/changing governmental regulations which create more hurdles to payment and conflict with best practices heath care clients contend are in patients' best interest.

Why did you choose the field of health law?

I was fortunate at my prior law firm to work with health care clients from the outset over 12 years ago, after doing similar legal work for non-healthcare clients. It started with MOB leasing work for a six hospital healthcare system, which expanded to other kinds of legal work for them. I enjoyed the work and learned more about the company's mission to serve patients with limited means, recruit quality doctors to California, obtain financing and address myriad legal issues facing heath care providers. Another



client of my former law firm was a SNF owner/operator. When the law firm's managing partner retired, the client asked me to take over the legal work, which included acquisitions, leasing, management services and other operational contracts, financing, and advice on what to do when companies with whom they did business, filed bankruptcy. I like that heath care affects everyone. I want to help healthcare providers succeed, provide good patient care, find cures and develop better treatments.

What's your secret talent that few know about?

During and after college I was a professional freestyle skier and competed nationally in mogul (bumps) and aerial competitions, when the sport was getting started.

M. Andrew (Drew) Woodmansee

Drew Woodmansee is the chair of the firm's intellectual property practice. He has 23 years of experience representing clients in high-stakes patent litigation throughout the United States. He is a veteran patent trial lawyer, having tried cases to verdict in jury trials and bench trials in federal district courts, as well as in Section 337 investigations before the U.S. International Trade Commission (ITC).

Drew primarily represents clients in the life sciences and health care fields, leading patent cases in the medical device, diagnostics, surgical equipment, and pharmaceutical industries. Most recently, he represented a manufacturer of continuous glucose monitors against allegations it infringed a competitor's patents. Drew led his client to a victory that invalidated all claims of one of the asserted patents at the Patent Trial and Appeal Board (PTAB). He also recently represented a manufacturer of 3D breast imaging systems and equipment in a suit against a competitor before the ITC.

How has your practice evolved in the last 5 years?

Well, the most obvious change is HLB as a firm is the same size as the SD office of my prior firm, so I am very happy to be in a more intimate setting. In terms of my practice, my clients over the past 5 years have been mostly in the fields of medical device, diagnostics, medical imaging and surgical equipment, whereas 10 years ago more of my clients were in the pharma space. The other main change stems from the America Invents Act (patent reform), which was passed in 2011 and became effective in 2012. Among other changes, it created a new administrative vehicle in the Patent Office by which parties can challenge the validity of issued patents before (theoretically) a more specialized court in a more efficient proceeding. That change has shifted much of patent litigation from the courts to the Patent Office, although that trend has slowed somewhat in the past 2 years.

What hot issues are your clients facing?

For clients in medical diagnostics, how can they protect their core technology in light of recent Supreme Court precedent interpreting Section 101 of the Patent Act. Courts have interpreted Section 101 to exclude from patent eligibility inventions that seek to patent "laws of nature, physical phenomena, or abstract ideas." The Federal Circuit (the nationwide appellate court for patent cases), has repeatedly held that many medical diagnostic patents are invalid under Section 101 since they merely claim laws of nature detected by otherwise routine steps (for example, methods for characterizing the risk of cardiovascular disease in an individual by determining the level of the enzyme myeloperoxidase (MPO) in a sample taken from the individual and comparing that level with MPO levels in persons not having cardiovascular disease). Given the importance of this technology to the public interest believe Congress must weigh in. Another hot IP area involves A.I. in the health care field.

Why did you choose the field of health law?

I used to do work for clients in the consumer electronics space, including cell phone manufacturers and cable/satellite providers. Those cases don't appeal to me in the same way cases in the healthcare field do. I started representing Dexcom (a manufacturer of continuous glucose monitors) in 2005. CGM was a relatively unknown technology then. Abbott sued Dexcom for patent infringement and sought to enjoin the launch of Dexcom's first product. We defeated the injunction, Dexcom launched, and it now has 80% of the U.S. CGM market. My greatest satisfaction is when—whether in conversation or after a lecture of presentation at a conference—a person tells me how the product has changed their life or the life of their spouse or child. I never had anyone thank me for helping them get a better cell phone or satellite TV. That is why I choose to focus on clients in life sciences/healthcare field.

What are the top three things in your bucket list?

1. Play a round of golf at Augusta National
2. Get a hole-in-one with a witness (I had one during a 7am round of golf by myself, but it doesn't count since no one saw it!)
3. Grow grapes and make my own wine

FIRM NEWS

Things happening at Hooper, Lundy & Bookman

BEST LAWYERS IN AMERICA RECOGNIZES 13 HLB ATTORNEYS AND TWO ATTORNEYS NAMED "LAWYER OF THE YEAR"

Hooper, Lundy & Bookman is pleased to announce that 13 of its attorneys have been recognized for their health law expertise in the 2020 Edition of Best Lawyers in America.

Additionally, Linda Kollar was named "Lawyer of the Year" for her work in the field of Administrative/Regulatory Law and Harry Shulman was named "Lawyer of the Year" for his work in the field of Health Care Law. This award recognizes the attorney who receives the highest overall peer-feedback in their practice area and geographic region.

According to Best Lawyers, recognition of these accomplishments is based on a peer-review survey process of legal professionals who gauge the specialized abilities of their colleagues within the same geographical and legal practice area.

Administrative / Regulatory Law

Los Angeles, CA
- Linda Randlett Kollar (Lawyer of the Year)

Health Care Law

Los Angeles, CA
- Lloyd A. Bookman
- David A. Hatch
- John R. Hellow
- Patric Hooper
- Linda Randlett Kollar
- Robert W. Lundy, Jr.
- Nina Adatia Marsden
- Charles B. Oppenheim

San Diego, CA
- Mark A. Johnson

San Francisco, CA
- Ross E. Campbell
- Steven Lipton
- Harry Shulman (Lawyer of the Year)
- Paul T. Smith

TOP PATENT LITIGATOR DREW WOODMANSEE JOINS HOOPER, LUNDY & BOOKMAN AS HEAD OF IP PRACTICE

M. Andrew "Drew" Woodmansee joined the firm as a shareholder in its San Diego office, where he will lead the firm's intellectual property practice. A seasoned patent litigator with 23 years' experience representing a broad range of health care and life sciences clients, Woodmansee expands and complements the firm's sophisticated health care litigation practice. He joins from Jones Day, where he was partner.

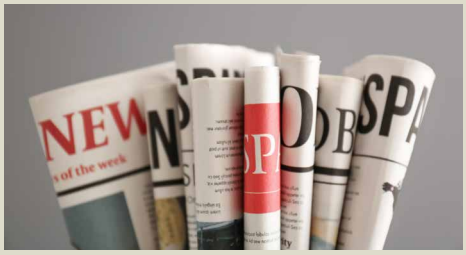
Woodmansee has spent more than two decades representing clients in high-stakes patent litigation throughout the United States, primarily in the medical device, diagnostics, surgical equipment, and pharmaceutical industries. A veteran trial attorney, Woodmansee has tried cases to verdict in jury trials, bench trials, and in Section 337 investigations before the U.S. International Trade Commission, as well as numerous cases for pharmaceutical clients under the Hatch-Waxman Act.

In addition to his client work, Woodmansee has long been involved in the San Diego legal community, having served on the board of directors for the San Diego Volunteer Law Program and the San Diego Gay and Lesbian Bar Association. He will bring this experience to bear at Hooper, Lundy & Bookman as the newest member of the firm's Diversity and Inclusion Committee.

HOOPER, LUNDY & BOOKMAN WELCOMES TOP TRANSACTIONAL LAWYER GARY TORRELL

Gary Torrell joined the firm's Business Department as a partner in its Los Angeles office. A seasoned transactional and litigation lawyer, he was most recently the Chair of the Business and Finance, Real Estate, and Creditors' Rights practices at Valensi Rose. He was previously in-house counsel at three companies: Chief Legal Officer at Downey Savings (a $16 billion, publicly-held, 2,500 employee, 200-branch bank); General Counsel to a privately-held $1 billion national real estate company; and Senior Counsel at City National Bank. Prior to this, he spent 12 years at Paul Hastings.

Gary has over 30 years of legal and business experience. His practice is a broad combination of specializations, including real estate, corporate, bankruptcy, lending, creditors' rights, and litigation in state and federal courts.



CALENDAR

DATE	EVENT
August 22	**Health Financial Systems User Meeting 2019, Boston. MA** Bob Roth presents **FY 2019 IPPS Legislative and Regulatory Update**
August 23	**National Academy for State Health Policy 2019 Conference, Chicago, IL** Jeremy Sherer participates in roundtable discussion on **Telemedicine: How States Can Advance Integrated Care**
September 12-13	**The Healthcare Roundtable for Chief Compliance Officers, San Diego, CA** Jeremy Sherer presents **Telehealth Contracting for Compliance Officers**
September 25-27	**American Health Lawyers Association Fraud Compliance Forum, Baltimore, MD** Bob Roth co-presents **Beyond Refunds: Coding Review, Error Rates, and Statistical Sampling under the 60 Day Overpayment Refund Statute and the Related Impact on Health Care Transactions** Lloyd Bookman co-presents, **Rules v. Sub-Regulatory Guidance — The Implications of the Allina and Kisor Decisions**
October 8	**HLB-Wolters-Kluwer Webinar Series (Part 4)** Bob Roth, Kelly Carroll, Monica Massaro and Alicia Macklin present **Looking Back and Looking Ahead — What's In Store for the Rest of 2019**
October 15	**Northeast Regional Telehealth Conference** Jeremy Sherer co-presents **Consumer Protection in Telehealth and Artificial Intelligence**
October 22-23	**HLB Managed Care Seminar, Los Angeles, CA and Berkley, CA** Hooper, Lundy & Bookman hosts Managed Care 2019 Update
November 5	**HCCA's 5th Annual Healthcare Enforcement Compliance Conference, Washington, DC** Charles Oppenheim presents, **Ask the Stark Law Professionals**
November 7	**5th Annual North Country Telehealth Conference: The Value of Virtual, Lake George, NY** Jeremy Sherer and Amy Joseph present **Regulatory Trends in Digital Health: Understanding Developments in Telehealth Reimbursement, Enforcement, and Interoperability**
November 10-13	**CAHF Annual Conference, Palm Springs, CA** Mark Johnson presents
December 3	**HLB Fraud and Abuse Seminar, Los Angele, CA** Hooper, Lundy & Bookman hosts Health Care Fraud and Abuse Update 2019

HLB
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