May 2021

Outlook: U.S. Health Care 2021

Tech and data drive new opportunities and liabilities

ReedSmith

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Introduction

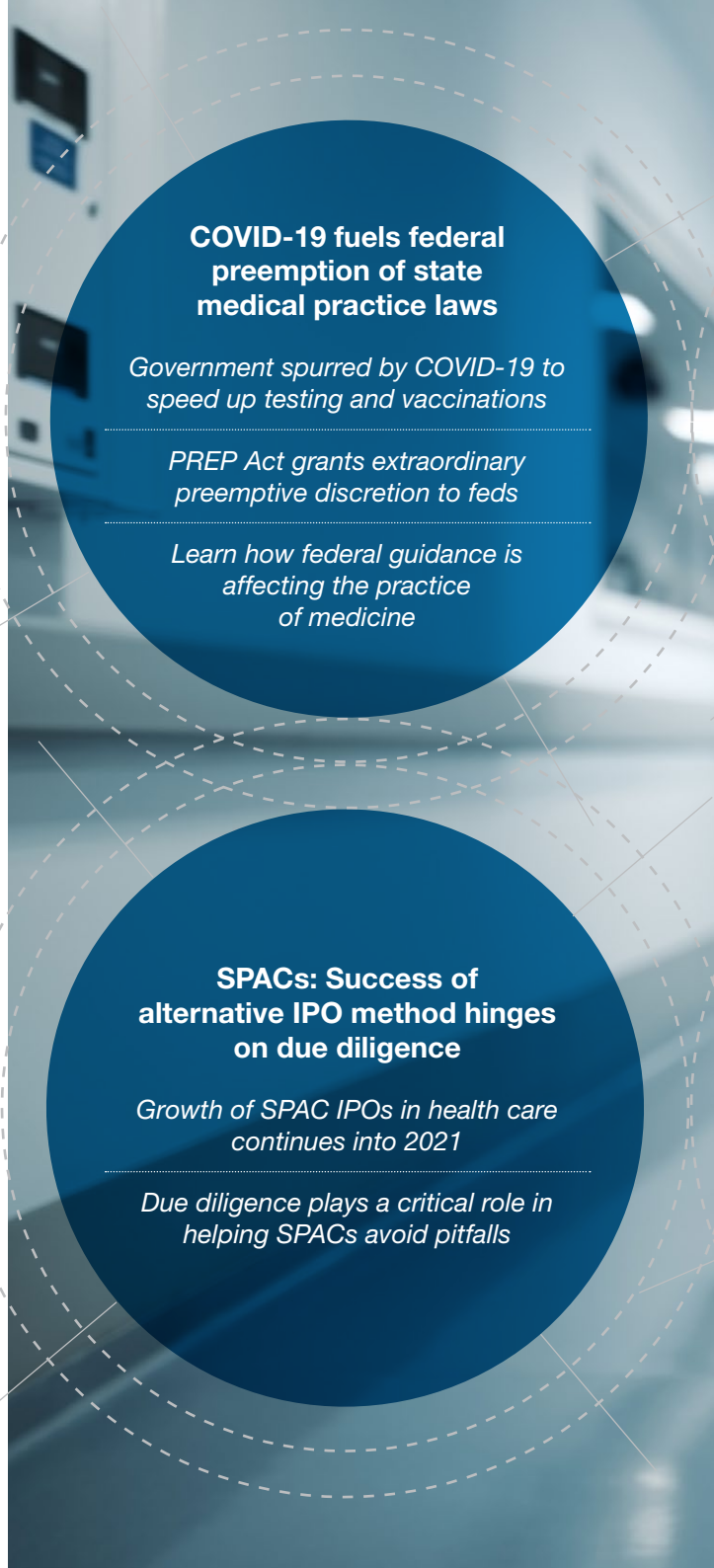
We may not be able to predict the future, but if we identify where and how we should be focusing attention and resources, we can lessen the cost and impact of changes in market conditions.

That is the approach we take as we give our perspective on the health care trends that industry participants in the United States should be watching for throughout 2021.

Outlook: U.S. Health Care 2021 features practical and timely insight that providers, manufacturers, distributors, pharmacies, health plans, or companies investing in this sector will likely put to use.

So many of the changing dynamics in our industry were caused by – or at the very least, impacted by – the COVID-19 pandemic. Much of what you will find here looks into a new array of legal issues that have come up in the past 12 months, but will be faced by the industry for the foreseeable future.

Many health care issues – including telehealth, the Stark Law and Anti-Kickback Statute, and diagnostic testing – certainly pre-date the COVID pandemic. But rather than merely picking them up where we left off, we look at them anew, taking into account not just the pandemic and the rise of new regulations, but also a mounting wave of digitization that's affecting health interactions of all kinds.



Final rules provide Stark and Anti-Kickback clarity in value-based arrangements

Fraud and abuse rules can be triggered if value-based arrangements are not properly designed and monitored

Rules do more to let health systems reward providers and suppliers for adopting cost-saving protocols and improve quality of care

Drug compounding: Alliances with telehealth and Big Tech proliferate

Big Tech has entered the pharmacy space and shaken up the compounding industry

Telehealth platforms have quickly expanded presence in the compounding industry

New entrants must appreciate the industry's unique history and regulatory landscape

Information blocking rule establishes new data sharing principles for health care industry

New rule requires providers and certain health IT companies to share electronic health information

Exceptions exist for preventing harm, privacy, security, infeasibility, among others

Enforcement framework, which includes civil money penalties, remains in flux

Diagnostic test supervision: CMS relaxes rules but also creates ambiguity

Long-time Medicare requirements that only physicians can supervise diagnostic tests are changing

Non-physician practitioners allowed to supervise more types of tests

Persistent ambiguities in the rules have had a chilling effect

Thank you for spending some of your time with us as we explore these important topics.

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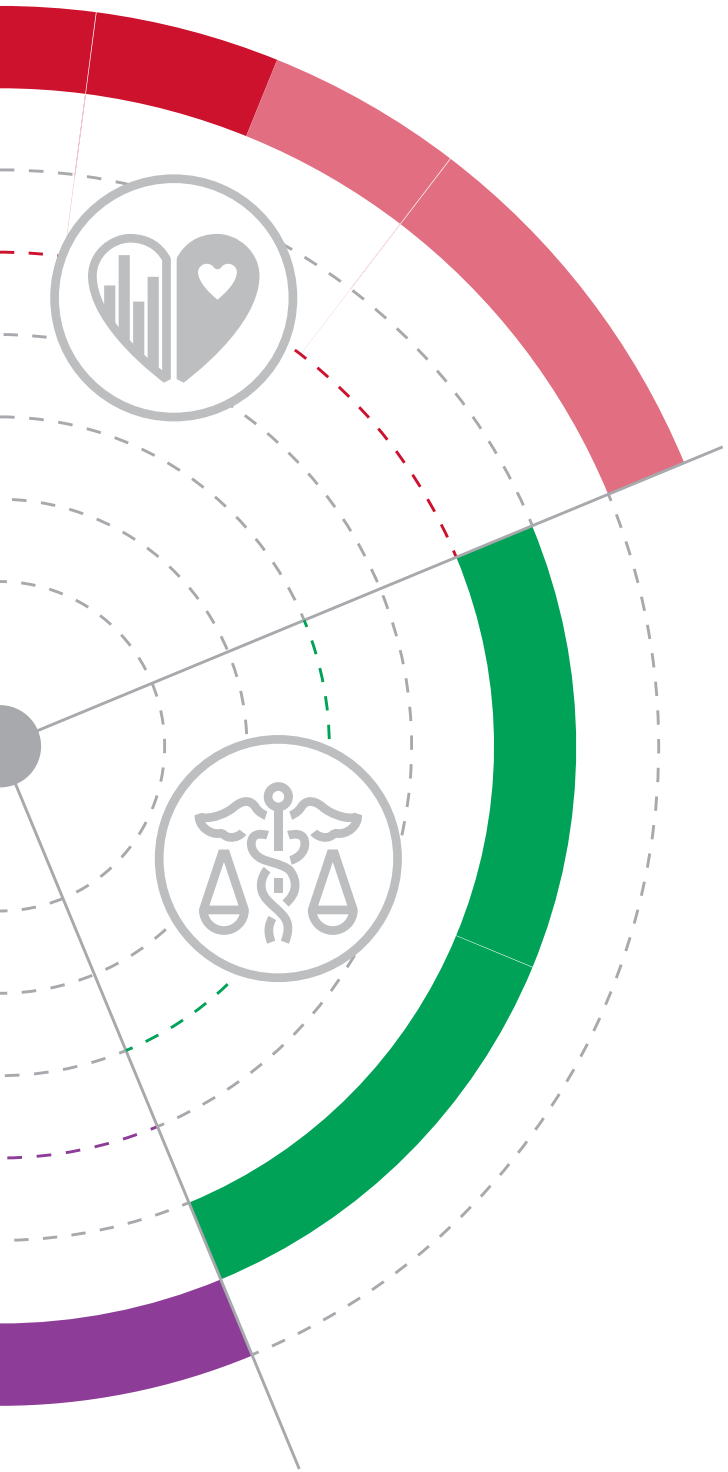
Partner and Co-Chair of Reed Smith's Life Sciences Health Industry Group
Washington, D.C.

Post-COVID trends and lessons learned

Future of value-based care



Intersection of health care and data

Evolving environment of health care delivery

COVID-19 fuels federal preemption of state practice-of-medicine laws

Takeaways

- Federal government is encroaching on state controls over the practice of medicine
- COVID pandemic created more reasons for federal preemption
- PREP Act grants extraordinary preemptive discretion to HHS

On February 26, 2020, as fears of a potential pandemic caused by COVID-19 spread across the globe, we argued that federal public health powers are ostensibly quite limited, as illustrated by the scope of quarantine powers granted to the U.S. Centers for Disease Control and Prevention. The article flagged the foreseeable risk that conflicts may arise between the federal government and the states over the application of quarantine and other public health powers.

A year later and many of these tensions have been pushed aside for the greater purpose of responding to the pandemic. In doing so, many long-standing principles of state regulation of the practice of medicine and other healing arts have been preempted. This article reflects on some lessons learned and the possible changes ahead, focusing on the federal government's COVID-19 testing proposal and the use of federal laws to respond to public health emergencies.

On January 21, 2020, COVID-19 first came to U.S. shores in Seattle; by mid-February 2020, a local nursing home had the first outbreak, which indicated that community spread was occurring. Other than short-lived controversy over whether to let a cruise ship dock in San Francisco, and some half-hearted air travel bans and screening, it was clear that quarantines were not going to be an effective tool to prevent the further spread of SARS-CoV-2. By March 11, 2020, the World Health Organization had declared a pandemic, and on March 13, 2020, President Donald Trump declared a national emergency, and health authorities switched strategies to detection and mitigation.

One of the first strategies implemented by the federal government was a widespread testing regime. On March 13, President Trump held an event in the Rose Garden where he announced a drive-through testing strategy involving the large retail pharmacy chains (plus one "big box" store). In this effort, the federal government declared that it would arrange for and manage all of the testing and would provide security, personal protective equipment (PPE), and collection kits. The pharmacies would host the sites, and their employees would collect specimens. The collected samples would be sent to third-party clinical laboratories, and the federal government would arrange for notifications of results to patients, all of this to be powered by a scheduling and management database that would be built by Google, which had "1,700 engineers working on the problem."

"These scope-of-practice limitations are generally absolute and cannot be circumvented by training, credentialing, or certification."

Most of this did not come to pass (at least not as proposed) in spite of best efforts by retailers – because the government could not source test kits or PPE, or provide any testing capabilities, and Google was never engaged to create a scheduling/management database. Nevertheless, the drive-through testing proposal raised a number of interesting questions. The use of retail pharmacy partners to quickly scale testing sites made sense given their geographic footprints, health care supply chain experience, and licensed pharmacists. But state law often restricts the ability of pharmacists to order and administer COVID-19 tests as these are activities characterized – by certain state laws – as beyond a pharmacist's scope of practice. These scope-of-practice limitations are generally absolute and cannot be circumvented by training, credentialing, or certification.

The practice of medicine – and other clinical practice – is regulated by the states. This concept was deemed so important (at one time) that it is enshrined as the very first paragraph of the Medicare Act, 42 U.S.C. section 1395, which prohibits any federal interference with the "supervision or control over the practice of medicine or the manner in which medical services are provided…" Even if we push aside this statement as a predicate assuagement for passage of a new government social welfare system, it is undisputed that state law sets the requirements for the practice of medicine and other healing arts. States supervise and license physicians, therapists, nurses, optometrists, hospitals, nursing homes, and other providers and clinicians. States decide (usually through professional boards) the scope of practice of each of these professions within the state. Indeed, and specific to the COVID-19 testing proposal, physicians and osteopaths have long opposed expansion of practice by pharmacists, qualified nurse practitioners, and other clinicians, with the American Medical Association even using the social media hashtag #stopthescopecreep. The numerous news articles covering these past debates or "battles" tend to use adjectives like "bitter" and "fierce" in describing scope-of-practice disputes.

Because the scope of practice is a state law issue, governors were urged to use their emergency powers to temporarily allow for an expansion of practice that would increase COVID-19 testing. A number of states issued orders to expand testing, usually to include pharmacists and pharmacy technicians. In spite of these efforts, however, many states did not act, which led the U.S. Department of Health and Human Services (HHS) to issue a series of directives under the PREP Act, 42 U.S.C. section 247d-6d, a post-9/11 law that was triggered by a March 17 declaration by the HHS secretary that a public health emergency existed under the PREP Act.

The PREP declaration confers broad immunity on covered persons from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure. The only exception is "willful misconduct." In its April 8, 2020, guidance, HHS took the position that the countermeasure is the COVID-19 testing and that ordering pharmacists are the covered persons, and they may receive immunity under the Act. In spite of this view of immunity, pharmacists were reluctant to risk their professional licenses on the basis of a guidance document, which led HHS to issue a formal advisory opinion on May 19, 2020.

"This article reflects on some lessons learned and the possible changes ahead, focusing on the federal government's COVID-19 testing proposal and the use of federal laws to respond to public health emergencies."

In this opinion, HHS explicitly took the position that state laws prohibiting pharmacists from ordering tests were preempted, writing that:

> *Because of that [PREP] authorization, "no State or political subdivision of a State may establish, enforce, or continue in effect with respect to [FDA-authorized COVID-19 tests] any provision of law or legal requirement that is different from, or is in conflict with, any requirement applicable under this section" and that "relates to…the prescribing, dispensing, or administration by qualified persons of the covered countermeasure."42 U.S.C. section 247d-6d(b)(8)(A).*
>
> *As explained above, any state or local law or legal requirement that prohibits or effectively prohibits licensed pharmacists from ordering and administering FDA-authorized COVID-19 tests are different from or in conflict with the declaration – and therefore, a legal requirement under the PREP Act. So during the effective period of the PREP Act declaration, a state or locality cannot establish, enforce, or continue any such legal requirements under the PREP Act's preemption provision.*

In a little-noticed footnote to this opinion, HHS argues that PREP grants extraordinary preemptive discretion to HHS:

> *When Congress intends to exempt state-licensing laws from its preemption provisions, Congress explicitly says so. See, e.g., 42 U.S.C. section 1395w-26(b)(3) ("The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency)" (emphasis added)); 8 U.S.C. section 1324a(h)(2) ("The provisions of this section preempt any State or local law imposing civil or criminal sanctions (other than through licensing and similar laws)" (emphasis added)). Congress did not do so in the PREP Act.* ***Instead, Congress gave the Secretary virtually unreviewable authority to immunize and designate a "qualified person" to use a "covered countered measure."*** (emphasis added).

Perhaps emboldened by the circumstances of the pandemic and the lack of pushback from state governments, HHS pushed ahead with numerous additional amendments and advisory opinions on related subjects, including telehealth, vaccination administration, and even decisions not to provide covered countermeasures.

For example, on the issue of telehealth and state law limitations on remote practitioners, **HHS wrote:**

> *To help maximize the utility of telehealth, the Secretary declares that the term "qualified person" under 42 U.S.C. 247d-6d(i)(8)(B) includes healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice. When ordering and administering Covered Countermeasures through telehealth to patients in a state where the healthcare personnel are not already permitted to do so, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients through telehealth* ***in the state where the healthcare personnel are licensed or otherwise permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures through telehealth is preempted****. Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.* (emphasis added).

"Telehealth is a good 'tip of a spear' to effect change on a nationwide basis, but so are testing issues as the need for point-of-care testing will likely continue into the near future."

While all of these preemptions are limited to covered countermeasures during the pandemic, we would note that one could take a very broad view of a covered countermeasure. It is also worth noting that this type of preemption does not act as a direct preemption of a specific scope of practice (which attracts more political attention), but instead allows for one state to drive the scope of practice in any state without regard to specialty. So a qualified nurse practitioner in a state with a broad scope of practice would be able to perform a service that might otherwise be reserved for physicians in the state where the patient is located.

In closing, as this article was written, vaccine manufacturers were testing COVID-19 vaccine booster shots with a likely deployment in the fall or winter of 2021. Assuming that these vaccine boosters will be purchased and distributed by the United States, then it would be likely that HHS will continue to renew the public health emergency declaration for purposes of PREP coverage. This potentially means another year of the preemption described above and also likely renewed executive orders and expansions under state law. Telehealth is a good "tip of a spear" to effect change on a nationwide basis, but so are testing issues as the need for point-of-care testing will likely continue into the near future. It will, of course, be interesting to see whether these scope-of-practice expansions are made permanent via federal or state legislation. Now that the precedent has been set, Congress may consider the benefit of some preemptive laws relating to scope-of-practice restrictions, at least for purposes of federal health care programs.

Deeper dive

Explore related content from Reed Smith lawyers:

Novel coronavirus: navigating US federal and state rules and regulations during a public health emergency, 12 February 2020 – Read the client alert

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Attack of the SPAC: Success of alternative IPO method hinges on due diligence

Takeaways

- The growth of SPAC IPOs in health care continues into 2021
- SPACs acquire multiple targets simultaneously – and enter into transactions with related entities, introducing new risks
- Due diligence plays an increasingly critical role in helping SPACs avoid pitfalls

Special purpose acquisition companies, or SPACs, have become a widely accepted vehicle by which companies can go public rather than through a traditional initial public offering (IPO). With nearly 300 SPAC IPO quarterly filings in Q1 2021, the SPAC market now towers over traditional IPOs by a four-to-one ratio. Shaquille O'Neal has his own SPAC (think about that – a ShaqSPAC!). In short, the market is undeniably hot. But SPACs are not new.

SPACs begin as publicly-listed blank-check companies whose purpose is to identify and purchase a private company. SPACs have approximately 24 months to identify and acquire a target company. Following the acquisition, the target company will be publicly listed.

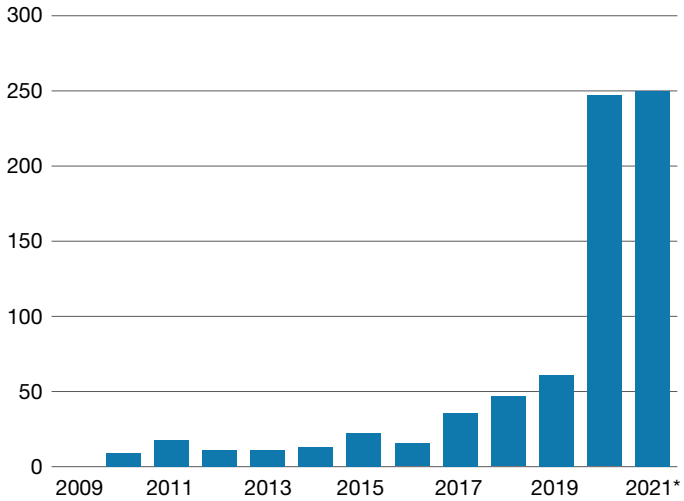
Trend within a trend

One of the recent trends in the SPAC market has been for SPACs to acquire multiple targets simultaneously. Historically, SPACs would avoid doing so because of the challenges involved – and the harsh consequences if the deal failed. In the current market, SPACs are trying to present a target company that is of sufficient scale to attract significant PIPE capital and retain the funds in the SPAC's trust account. Sometimes a particular target is too small, or greater value can be added by rolling multiple targets into the SPAC. Hence the new trend.

With this new trend, one must consider specific challenges, including timing of the closings, conditions to closing, consideration, valuation, exclusivity, and reps and warranties.

SPAC Boom in the United States

Number of SPAC IPOs in the United States, 2009-2021



*as of March 11, 2021
Special purpose acquistion company (SPAC)
Source: SPAC Insider

statista

“The high-risk, high-reward nature of this business means that risks can present themselves at any moment, and proper due diligence must be performed to identify any such risk or signs of such risk.”

Another surprising trend is deals with related-party transactions. Specifically, how does a SPAC navigate a potential acquisition of a company affiliated with the SPAC’s sponsor or management? Some vital issues to consider include pre-IPO discussions between the SPAC and the target, the fairness opinion, and involvement of the conflicted individuals or entities in the process on both sides of the deal.

With that said, the unique advantages of SPAC transactions do not negate the need for proper due diligence. While the importance of due diligence cannot be understated for any type of deal, the risk that is associated with inadequate or less-than-thorough due diligence is especially great for biotechnology companies because the companies’ products can directly affect their end-customers’ (patients’) health, and because they are heavily regulated by multiple government agencies. The high-risk, high-reward nature of this business means that risks can present themselves at any moment, and proper due diligence must be performed to identify any such risk or signs of such risk.

When engaging in a SPAC acquisition, it is typical to perform diligence on several areas that can pose significant risks to investors. These include the below.

Promotional practices

Companies’ promotional practices can have serious implications on whether a product can obtain marketing authorizations from the U.S. Food and Drug Administration (FDA), and on whether the product may become subject to post-marketing enforcement actions from FDA. Companies that fail on compliance are more likely to find themselves liable for marketing unapproved products, off-label promotion, or misrepresentation of the product’s safety and effectiveness.

In certain cases, unlawful promotional practices can trigger fraud and abuse cases from federal program administrators, and other lawsuits from private litigants. These can pose great risks to the company and the SPAC entity even after the transaction closes. While not all noncompliance will result in the deal being scrapped, certain unlawful promotional practices, depending on the potential risk posed by such practices, could be major red flags that sink a deal.


“With this new trend, one must consider specific challenges, including timing of the closings, conditions to closing, consideration, valuation, exclusivity, and reps and warranties.”

Compliance with clinical trial regulations

For biotechnology companies, ensuring compliance with FDA regulatory requirements pertaining to clinical trials, in particular with good clinical practice, informed consent protections, proper management of financial conflicts of interest, and adherence to institutional review board (IRB) requirements, among others, is critical. Noncompliance may result in FDA refusing to review results of the noncompliant clinical trial or lead to enforcement actions by FDA and state agencies. In addition, litigation and reputational risks are associated with study subjects whose rights are not adequately protected.

Government registrations and licenses

In addition to FDA, the federal government and many state governments require biotechnology companies to obtain and maintain certain licenses when engaging in production or performance of certain drugs or laboratory services. For example, state governments often require facilities that produce drugs (including both finished forms and active pharmaceutical ingredients) to be registered or licensed. If a facility performs laboratory services – for example, diagnostic services on samples that are received from health care providers – that facility may need to hold a CLIA certificate.

Failure to comply with these requirements can result in negative publicity as well as potential enforcement actions. With that said, these requirements may not apply to companies that produce only investigational drugs, which is the case for many early-stage biotechnology companies. Thorough due diligence is necessary to determine the exact set of requirements that is applicable to such companies.

Recalls, market withdrawals, and adverse events

It is also critical to request and assess information related to any recalls, market withdrawals, or adverse events associated with the biotechnology product or the company's other products, as history often serves as a predictor of current and future compliance. This information can identify potential risks with the company's product, and sometimes more importantly, whether the company is complying with FDA regulations and policies. The process can uncover red flags, shed light on opportunities for improvement, and ultimately help reduce the risk for the company in the future.

SPACs certainly offer unique advantages for companies in the cash-intensive biotechnology industry, including potentially higher valuations. But thorough due diligence remains important as ever, as without thorough diligence, all parties, including investors, may be exposed to significant risk.

Deeper dive

Explore related content from Reed Smith lawyers:

How SPACs Are Changing the IPO and M&A Markets, 26 August 2020 – Watch the webinar

"The process can uncover red flags, shed light on opportunities for improvement, and ultimately help reduce the risk for the company in the future."

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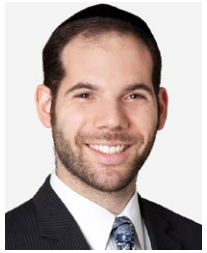

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Stark and Anti-Kickback final rules provide clarity and flexibility to value-based care

Takeaways

- As a foundation for protection, establish a VBE, either through a separate risk-bearing entity or a collaboration between two persons or entities
- Determine VBE participants and value-based activities (note: referrals and marketing do not qualify)
- Evaluate nature of VBA remuneration to assess protection options
- Monitor arrangement to ensure continued compliance with applicable Stark Law exception and AKS safe harbor

This overview is designed for health care stakeholders currently engaged, or seeking to engage, in value-based arrangements that implicate the federal Stark Law and Anti-Kickback Statute (AKS). In November 2020, the U.S. Department of Health and Human Services (HHS) released coordinated final rules for both laws, which we have previously covered in significant detail (Read about the October 2019 proposed rule; More on the proposed rule and the November 2020 final rule).

These final rules primarily aim to remove obstacles to value-based care, which enables payers and health systems to reward health care providers and suppliers for adopting cost-saving protocols, avoiding waste, and improving quality of care. Both the Stark Law and AKS were developed to address fraud and abuse concerns in a predominantly fee-for-service health care reimbursement environment. As a result of increased interest and investment in value-based care, HHS recognized the need for new exceptions and safe harbors to provide flexibility for value-based arrangements.

The new final rules are complicated. This piece therefore seeks to provide a high-level roadmap to help health care providers and companies that are considering structuring value-based arrangements.

"The rules allow flexibility in establishing the accountable body or person overseeing the VBE, as well as a governing document describing the VBE."

Who qualifies for protection?

As a threshold matter, value-based participants must be part of a value-based enterprise
Value-based enterprise (VBE): At least two persons or entities that collaborate, and are accountable, to achieve improved care coordination, quality, or efficiency for a defined patient population by taking, or refraining from taking, an action tailored to that improvement. The rules allow flexibility in establishing the accountable body or person overseeing the VBE, as well as a governing document describing the VBE.
VBE participant: An individual or entity that engages in at least one value-based activity as part of a VBE. For purposes of the AKS, this does not include a patient acting as patient.
Ineligible entities under AKS: With a narrow exception available to "limited technology participants" that are under the care coordination safe harbor, the AKS value-based safe harbors deem the following entities ineligible for protection: (i) pharmaceutical companies; (ii) pharmacy benefit managers; (iii) laboratory companies; (iv) compounding pharmacies; (v) device manufacturers or medical supply companies; (vi) durable medical equipment, prosthetics, orthotics, and supplies companies; and (vii) medical device distributors and wholesalers. No similar exclusion applies for the Stark Law exceptions.

What is protected?

Only certain arrangements, activities, and populations are eligible for protection under the Stark and AKS value-based framework
Value-based arrangement (VBA): An arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (i) the VBE and at least one of its VBE participants, or (ii) VBE participants in the same VBE.
Value-based purpose: Deliberate organization of patient care activities and sharing of information between VBE/VBE participants or VBE participants/patients designed to achieve safer, more effective, or more efficient care to improve health outcomes for a target patient population.
Value-based activities: If reasonably designed to achieve a value-based purpose, the: (i) provision of an item or service, (ii) taking of an action, and/or (iii) refraining from taking an action.
Target patient population (TPP): An identified patient population selected in advance using legitimate and verifiable criteria that: (i) are set out in writing and (ii) further the value-based purpose of the VBE. No cherry-picking or lemon-dropping.

How do parties protect a VBA?

Increasing financial risk met with increasing flexibility

AKS safe harbors	Stark exceptions
Care coordination arrangements No financial risk required so long as the VBA is directly connected to the coordination and management of care for the TPP (e.g., patient monitoring, patient diagnostic activities, patient treatment, predictive analytics, etc.), but the safe harbor only protects in-kind contributions. Note that there is express requirement to evaluate and modify arrangement at least annually.	**Any value-based arrangements** Unlike the AKS, the Stark Law protects exchange of **monetary** remuneration under a **commercially reasonable** VBA so long as it is documented in a signed writing that demonstrates value-based activities and its relationship to value-based purposes, along with a methodology to calculate remuneration, among other requirements. Note that, with the rule's clarification of "commercial reasonableness," the parties can look to their unique needs in evaluating compliance with that requirement. Note also the express requirement to evaluate and modify at least annually.
Substantial downside financial risk Protects in-kind and monetary remuneration and serves as the middle-ground financial risk model. The VBE can assume "substantial downside financial risk" from a payer via one of the following methodologies: (i) shared savings and losses, (ii) episodic payment, or (iii) VBE partial capitation. Importantly, each VBE participant must "meaningfully share" in the VBE's risk, whether by risk-sharing payments or by partial capitation.	**Substantial downside financial risk** The physician assumes meaningful downside financial risk (i.e., at least 10 percent) under a methodology that is set in advance in a signed document that describes the nature and extent of the downside risk. Risk is defined as risk to the entity with which the physician has a compensation relationship, not a payer.
Full financial risk Protects both in-kind and monetary remuneration and includes more "flexible" conditions and the greatest opportunity to innovate. Under a written agreement, the VBE assumes full financial risk on a prospective basis from a payer for the cost of **all** covered patient care and services for a defined population **for at least one year**. The parties phase in full risk after entering into a VBA, subject to safe harbor requirements.	**Full financial risk** As with the AKS, a Stark Law exception protects both in-kind and monetary remuneration and includes more "flexible" conditions. The VBE must assume full financial risk from a payer for the duration of the VBA. The parties phase in full risk after entering into a VBA, subject to exception requirements.

Deeper dive

Explore related content from Reed Smith lawyers:

Value-based changes under the Stark Law and Anti-Kickback Statute final rules: What the new exceptions and safe harbors mean for your business, 19 January 2021 – Watch the webinar

Deeper dive

Explore related content from Reed Smith lawyers:

The wait is over: The final rules to modernize Stark Law and Anti-Kickback Statute are here, 23 November 2020 – *Read the in-depth article*

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“These final rules primarily aim to remove obstacles to value-based care, which enables payers and health systems to reward health care providers and suppliers for adopting cost-saving protocols, avoiding waste, and improving quality of care.”

Information blocking rule establishes new data sharing principles for health care industry

Takeaways

- Disclosures of electronic health information (EHI) permitted by HIPAA and state law are now required (unless an exception applies) under new rule
- Providers and certain health IT companies must strategically evaluate how to protect IP interests yet maintain competitively neutral EHI data sharing practices
- Enforcement framework, which includes civil money penalties, remains in flux

Who is the rightful owner of electronic health information? Who should control when, how, and with whom that information is shared? These are critical, and valuable, questions for an industry with a compound annual growth rate of data that exceeds manufacturing, financial services, and entertainment and media.

In its information blocking rule, the Office of the National Coordinator for Health Information Technology (ONC) offers a definitive response – **the patient** – and responds to concerns that some individuals and entities are engaging in practices that unreasonably limit the availability, interoperability, and use of patients' electronic health information.

Key stakeholders in the health care industry – providers and certain health IT companies and developers – are now **prohibited** from engaging in practices likely to interfere with the appropriate access, exchange, or use of patients' electronic health information.

Under the new rule, if the Health Insurance Portability and Accountability Act of 1996 (HIPAA) or applicable state privacy laws **permit** the disclosure of electronic health information, the information blocking rule likely will **require** such disclosure. The rule does include important exceptions that offer regulated actors certainty that their practices will not be considered information blocking when meeting the conditions of one (or more) exception. Yet, leveraging these complex exceptions will require advance planning.

What is information blocking?

Information blocking is a business practice **likely to interfere with, prevent, materially discourage, or otherwise inhibit the access, exchange, or use of electronic health information** (EHI). Information blocking does not include practices that either (1) are required by law or (2) comply with an exception to the information blocking rule.

Put simply, information blocking encompasses activities that make the access, exchange, use, or interoperability of health data more difficult. The definition also encompasses an intent requirement, which is different depending on the identity of the regulated actor.

Who must comply, and what are the associated intent requirements?

The information blocking rule applies to health care providers, health information networks (HINs) and health information exchanges (HIEs), and ONC-certified health IT developers.

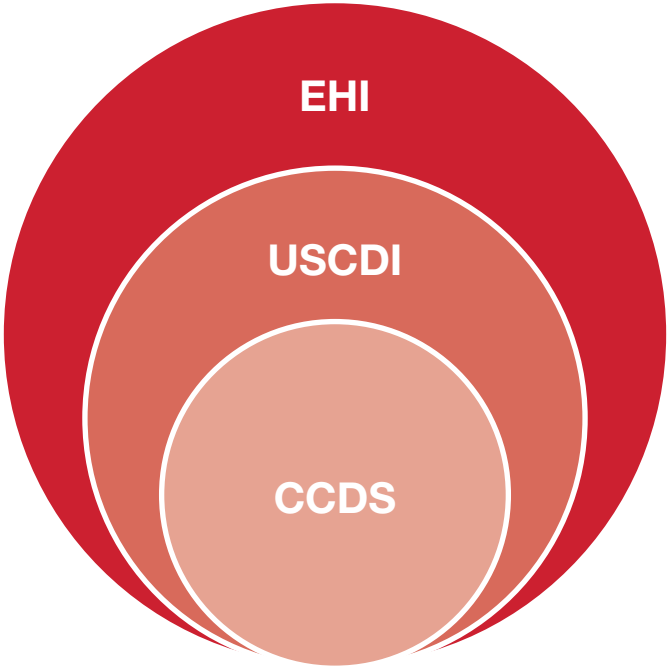
For health care providers, a practice meeting the regulatory definition will be considered information blocking if the health care provider knows such practice to be unreasonable and likely to interfere with access, exchange, or use of EHI.

For ONC-certified health IT developers, HINs, or HIEs, a practice meeting the regulatory definition will be considered information blocking if the regulated actor knows, or should know, that such practice is likely to interfere with the access, exchange, or use of EHI.

Developers must take note that if their products include any ONC-certified health IT, they must comply with the information blocking rule with respect to all of their health IT products and services – even those that are not certified.

What is electronic health information (EHI)?

The information subject to the information blocking rule will change over time as the industry prepares for full compliance.



USCDI

Until Oct. 5, 2022, EHI is limited to the data elements included in the **U.S. Core Data Interoperability (USCDI) standard**, version 1. The USCDI differs from and replaces the Common Clinical Data Set (CCDS) standard – most notably through the addition of clinical notes – that is referenced in ONC's existing certification criteria for certified health IT.

EHI

As of Oct. 6, 2022, EHI is defined as **electronic protected health information (ePHI) included in a designated record set** – in other words, ePHI to which a patient has a right of access. Although this definition draws upon key concepts and definitions from HIPAA, it applies regardless of whether HIPAA applies.


“These are critical, and valuable, questions for an industry with a compound annual growth rate of data that exceeds manufacturing, financial services, and entertainment and media.”

"The rule does include important exceptions that offer regulated actors certainty that their practices will not be considered information blocking when meeting the conditions of one (or more) exception."

What are the exceptions?

There are eight exceptions to the information blocking rule, which can be broken down into two categories: (1) exceptions that involve **not fulfilling** requests to access, exchange, or use EHI and (2) exceptions that involve procedures for **fulfilling** requests to access, exchange, or use EHI.

Exceptions that involve not fulfilling requests to access, exchange, or use EHI

1. Preventing harm exception
Engaging in reasonable and necessary practices to prevent harm to a patient (or another)

2. Privacy exception
Not fulfilling a request in order to protect an individual's privacy

3. Security exception
Interfering with the access, exchange, or use of EHI in order to protect the security of EHI

4. Infeasibility exception
Not fulfilling a request due to the infeasibility of the request

5. Health IT performance exception
Taking reasonable and necessary measures to make health IT temporarily unavailable or degrading the health IT's performance for the benefit of the overall performance of the health IT

...provided certain conditions are met

Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI

6. Content and manner exception
Limiting the content of a response to a request to access, exchange, or use EHI, or changing the manner in which the request is fulfilled

7. Fees exception
Charging fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI

8. Licensing exception
Licensing interoperability elements for EHI to be accessed, exchanged, or used

...provided certain conditions are met

Must regulated actors license their intellectual property to requestors of EHI?

No, but operationalizing a compliance strategy that protects investments in health IT will require advance planning and discipline. Regulated actors cannot assert ownership rights to the EHI itself, which belongs to the patient. Furthermore, licenses to interoperability elements – proprietary data formats, processing mechanisms, and exchanges – must be offered on nondiscriminatory and competitively neutral terms. In other words, these terms must be based on objective and verifiable criteria that are uniformly applied and not related to the requestor's intended use of the EHI.

How will the information blocking rule be enforced?

Enforcement of the rule will depend on the type of regulated actor, and many of the details are yet to be finalized.

Health care providers could be subject to appropriate disincentives to be determined in future rulemaking by the Department of Health and Human Services (HHS). Additionally, the Centers for Medicare & Medicaid Services (CMS) will publicly report eligible clinicians, hospitals, and critical access hospitals that may be information blocking based on their attestation to certain Merit-based Incentive Payment System (MIPS) and Promoting Interoperability Program requirements, starting with 2019 performance year data.

Developers of certified health IT, HINs, and HIEs could be subject to civil monetary penalties (CMPs) up to $1 million per violation levied by the HHS Office of Inspector General (OIG), as well as separate enforcement by ONC related specifically to certified health IT.

OIG is scheduled to publish its final rule implementing information blocking CMPs in August 2021. Enforcement of information blocking CMPs will not begin until the CMP rule is final. Further, the OIG will exercise enforcement discretion such that conduct occurring before the CMP rule is final will not be subject to information blocking CMPs.

Deeper dive

Explore related content from Reed Smith lawyers:

Information Blocking, Interoperability, and Patient Access – How to prepare for the new rules now, 11 March through 6 May 2021 – Watch the five-part webinar series

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Compounding is the latest darling of telehealth and Big Tech, but is Silicon Valley prepared for the regulation that comes with it?

Takeaways

- The COVID-19 pandemic accelerated key trends in the compounding industry
- Telehealth platforms have rapidly spread into the compounding space
- Big Tech has entered the pharmacy space and shaken up the compounding industry
- New entrants must appreciate the unique regulatory landscape of the compounding space

Compounded medications and the pharmacies that prepare them have long been at the forefront of innovation and health care management. Over the last year, however, the COVID-19 pandemic has accelerated trends that have been gaining traction in the compounding industry for some time, namely, telehealth and the entry of Big Tech and big data.

The compounding industry has changed in two key ways, by: (1) complementing the customized and personal care offered via telehealth platforms and (2) adapting to the entry of large name-brand tech companies. These trends will undoubtedly continue into the next year and beyond.

However, many of these new entrants to the compounding industry may not appreciate the rules and regulations that apply to compounded medication. Compounded medication occupies a unique space in the human and animal health care market and in the drug supply chain by satisfying patient treatment needs when a commercially available drug is unavailable or inappropriate for treatment. That unique space, however, comes with unique regulatory requirements.

Compounding pharmacies must comply with multiple layers of regulations, including portions of the federal Food, Drug & Cosmetic Act (FDCA), state statutes and regulations governing the practice of pharmacy, controlled substance regulations, and compounding standards developed by organizations like the U.S. Pharmacopeia (USP). Regulation is even more nuanced when it comes to compounding medication for animals. As new entrants try to make the most of rapidly changing technology and ever-evolving ways to deliver medical care to patients, it becomes increasingly important to stay apprised of state and federal regulations governing compounding.

Telehealth expansion

Over the last several years, telehealth companies like Roman, Curology, Hims & Hers Health, and Dermacare, among many others, that offer prescription and over-the-counter medications typically through a subscription or membership program have rapidly expanded their presence in the compounding industry. Typically, these companies do so either by partnering with existing compounding pharmacies to prepare medications, or building their own in-house compounding pharmacies to meet patient need. This trend accelerated in 2020 as many telehealth companies capitalized on increased consumer demand during the COVID-19 pandemic not only for telehealth visits with medical professionals but also for tailored treatments comprising everything from skin creams, to erectile dysfunction treatments, acne medication, and hair loss treatments.

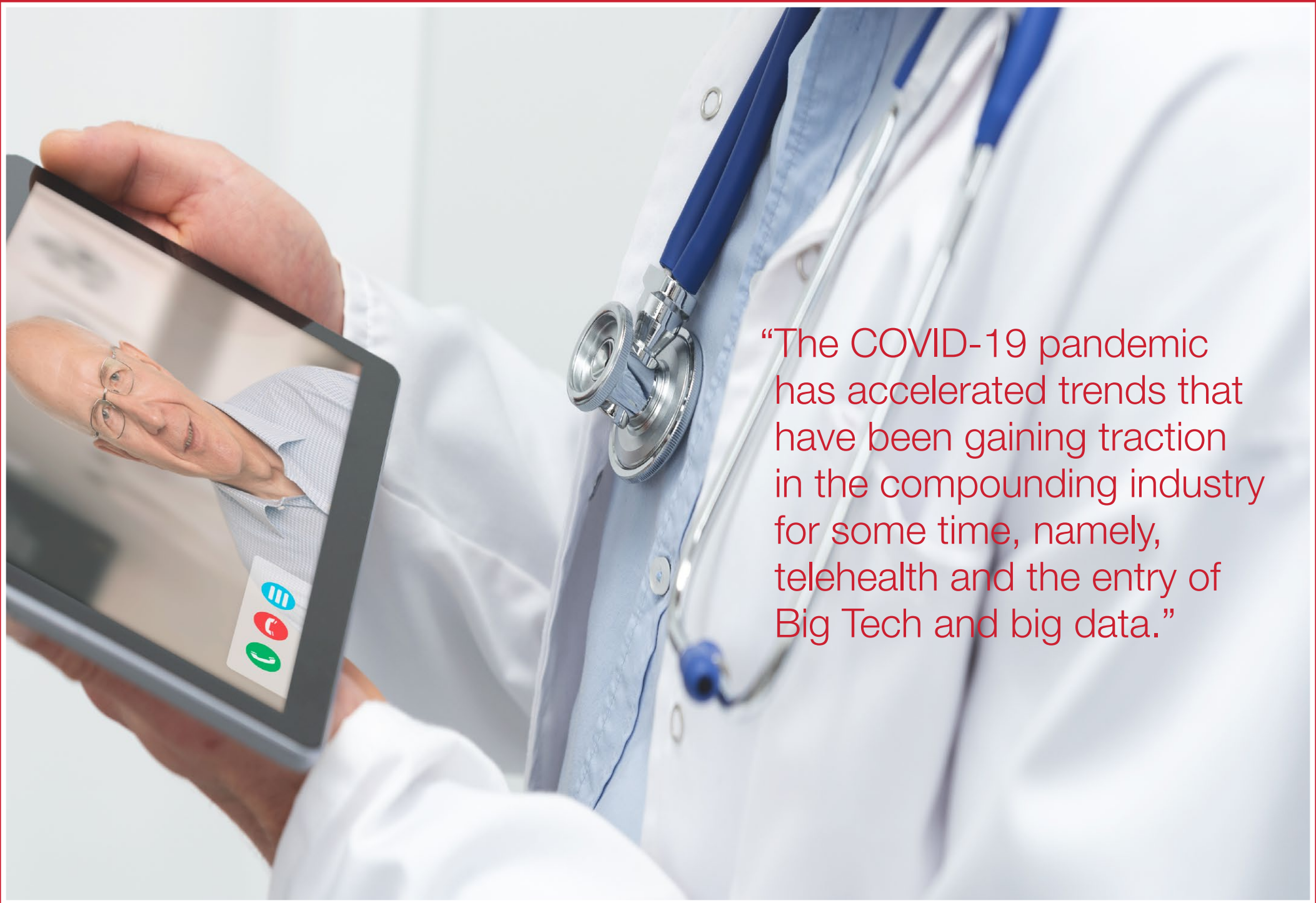
These tailored treatments are not possible without prescriptions for compounded medication from licensed medical professionals, and, as a result, telehealth companies have turned to the compounding industry to provide a conduit to meet patient need. However, even if these telehealth companies are not preparing the compounded medication themselves, they must be aware of the rules and regulations governing the practice of pharmacy and of compounding regulations. Failure to understand the industry could cause disruptions in service and scrutiny from regulators.

Big Tech enters the pharmacy space

Several national and multinational e-commerce and technology businesses that had no prior involvement with human or animal health care have recently entered the pharmacy space with the goal of becoming big players in the industry. For example, a leading online pet store, Chewy, recently opened its own licensed compounding pharmacy. Likewise, Amazon recently launched its own digital pharmacy, Amazon Pharmacy, and Walmart has expanded its online pharmacy presence into specialty pharmacy services and pet health pharmacy services. It is likely only a matter of time before other e-commerce businesses enter the pharmacy and compounding spaces.

Many of these Big Tech entrants that operate on a national scale will need to ensure that they comply with federal law and state regulations governing the practice of pharmacy. They will need to navigate, among other things, online pharmacy laws, controlled substance regulations, and laws governing practitioner-patient relationships. Without a solid foundation in regulatory compliance, Big Tech will find itself at the mercy of state or federal regulators, which could result in significant damage to their pharmacy businesses.

“Many of these Big Tech entrants that operate on a national scale will need to ensure that they comply with federal law and state regulations governing the practice of pharmacy.”


“The COVID-19 pandemic has accelerated trends that have been gaining traction in the compounding industry for some time, namely, telehealth and the entry of Big Tech and big data.”

New entrants must understand the risks of wading into the compounding space

There are a lot of advantages to entering the compounding pharmacy space, including the ability to create customized medications without going through the U.S. Food and Drug Administration's (FDA's) costly new drug approval process and to avoid certain burdensome health care laws (as most compounding pharmacies do not accept or bill insurance). However, in 2012, New England Compounding Pharmacy was involved in a meningitis outbreak that was linked to 76 deaths. This incident made national headlines, and, since that time, compounding pharmacies across the country have faced increased federal and state regulatory scrutiny.

For example, in 2013, Congress amended the FDCA to recognize two types of compounding facilities: (1) traditional compounding pharmacies and (2) outsourcing facilities. Each type of facility has unique federal guidelines governing the circumstances and conditions under which it can compound medication. The FDA has published multiple guidance documents over the past several years reflecting its current thinking on compounded medications.

There are also 51 different sets of state regulations (including the District of Columbia) governing the practice of pharmacy and compounding. These state regulations are ever evolving and require constant tracking and review to ensure that compounders remain on top of changes. Certain states, like California and New Mexico, have even begun to impose their own compounding standards on compounded medication that are, in certain ways, more onerous than those recommended by the USP.

In addition, we are seeing state and federal regulators move to address the expansion of telehealth and online pharmacy practice into the compounding space. Over the past year alone, we have seen:

- Increased regulatory attention to compounders' responsibilities as it relates to telehealth and the need to ensure that appropriate patient–practitioner relationships exist, especially when those relationships may be established entirely by virtual means;
- Fewer geographic restrictions on where compounding pharmacies can dispense medications when the provider treated the patient via telehealth; and
- More state-specific and DEA-specific guidance, temporary waivers, and temporary rules setting out the regulators' current thinking on telehealth and compounding and providing insight into formal regulations yet to come.

Thus, whether a health care platform intends to partner with third-party compounding pharmacies or to bring compounding processes in-house, without a real appreciation for the regulatory space that compounding pharmacies occupy, these companies could find themselves on the wrong side of state and federal regulators.

"We are seeing state and federal regulators move to address the expansion of telehealth and online pharmacy practice into the compounding space."

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Diagnostic test supervision: CMS relaxes rules but also creates ambiguity

Takeaways

- The long-time Medicare requirements that only physicians can supervise diagnostic tests are changing
- CMS relaxed the supervision requirements permitting non-physician practitioners to supervise certain types of tests, but left ambiguity in the new rules

Until recently, strict Medicare rules allowed only fully licensed physicians to take responsibility for the supervision of diagnostic tests. The Centers for Medicare and Medicaid Services (CMS) this year revised these long-standing rules, handing an expansion of purview to non-physician practitioners. But unfortunately, ambiguities in the drafting of the rule might have created compliance confusion on which levels of diagnostic tests allow supervision under the more flexible requirements.

As early as January 2019, CMS began to offer more flexibility in how diagnostic tests could be performed and who could take responsibility for their supervision. The first step toward flexibility that month was recognition that radiologist assistants (RAs) and radiology practitioner assistants (RPAs), who have higher levels of training, should be allowed to perform Level 3 tests even when the physician is not in the room, so long as the RAs and RPAs act within their scope of practice under state licensing laws. Not all states have defined such licensure for these practitioners, but the vast majority of states have such rules, facilitating increased flexibility in the performance of certain image-guided tests.

Pandemic brought change

In addition to expanding the role of RAs and RPAs, the COVID-19 public health emergency created a need for CMS to liberalize long-standing requirements that only fully licensed physicians could supervise many tests. CMS did this first on an interim basis and then, later, permanently. But, as we discuss below, the actual language of the new rules adopted this year raises questions as to how they should be applied.

"Changes in clinical practice, safety protocols, and equipment have caused stakeholders, including CMS, to reconsider the supervision rules."

Expanded purview for non-physician practitioners

The interim rule released in 2020 allowed for the first time, during the public health emergency, nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs), and certified nurse-midwives (CNMs) – collectively referred to by CMS as non-physician practitioners (NPPs) – to supervise diagnostic tests.

The interim rule change applied to tests performed in physician offices, hospital outpatient departments, and provider-based facilities. Only in the independent diagnostic testing facility setting were these NPPs still barred from supervising diagnostic tests.

As a result, during the public health emergency, no physician presence was required, even for Level 2 and Level 3 tests, if an NPP provided the necessary supervision of the technologist performing that test.

These reforms created considerable anticipation in the diagnostic imaging industry that CMS would extend the relaxed requirements when it created new permanent rules. As anticipated, CMS made such changes in its 2021 rules, but whether they fully accomplished these reforms is an open question.


“As early as January 2019, CMS began to offer more flexibility in how diagnostic tests could be performed and who could take responsibility for their supervision.”

Supervision rule: Is change overdue?

The supervision rules have not kept pace with the skills and training of ancillary personnel such as radiologic technologists and radiologist assistants.

The experience and capabilities of advanced practice providers that CMS refers to as non-physician practitioners have evolved as well.

When the supervision rules were created in the late 1990s, many advanced diagnostic imaging services (MRI, CT, and PET) were in their relative infancy, and the mandate that only physicians could supervise these tests was accepted as appropriate.

Changes in clinical practice, safety protocols, and equipment have caused stakeholders, including CMS, to reconsider the supervision rules.

Failing on supervision can be costly

Diagnostic imaging facilities have had to be cognizant of these rules and how to manage the performance of the tests they furnish. Failure to provide the appropriate level of supervision for a diagnostic test can render the service not "reasonable and necessary" and, therefore, not reimbursable under Medicare rules. More concerning, failure to provide for diagnostic test supervision consistent with Medicare's requirements has resulted in fraud and abuse allegations by the government that claims submitted by various providers for such testing services were false claims. Those investigations often have led to substantial monetary settlements and corporate integrity agreements with the government that often accompany such settlements.

Medicare rules prescribed that physicians alone could provide general supervision of plain film X-ray, ultrasound studies, nuclear medicine scans, and non-contrast MRI and CT services. And when contrast media was administered to enhance the image quality of an MRI or CT scan, Medicare demanded the on-site presence and direct supervision by a physician for these "Level 2" diagnostic tests. When those contrast MRI and CT studies were performed in independent diagnostic testing facilities, Medicare program integrity rules required the supervising physician to be "proficient" in the performance and interpretation of that these tests, effectively mandating the on-site presence of radiologists for those procedures furnished in independent diagnostic testing facilities (IDTFs).

Additionally, studies that make use of real-time fluoroscopic imaging guidance, such as barium swallow studies, arthrography, or myelography, required even greater physician presence. These fluoroscopic-guided services are referred to as "Level 3" tests that require the supervising physician to be present in the room throughout the performance of the test.

Confusion in the 2021 Medicare physician fee schedule

In its 2021 Medicare physician fee schedule rule, CMS stated that **all** diagnostic tests are supervised by physicians or, to the extent permitted by state law, one of the agency's designated NPPs.

Despite that apparently clear statement of regulatory policy, language promulgated in the final rules stated that physicians provide general supervision, with no mention of NPPs. Also, seemingly contradicting the rule change to permit all tests to be supervised by NPPs, CMS stated that Level 3 tests requiring personal supervision means a physician must be in attendance in the room throughout the performance of the test. Yet again, no reference was made as to whether the various categories of NPPs were permitted to supervise Level 3 tests. However, CMS has left language in place in the rules that physicians may provide direct rather than personal supervision when Level 3 tests are performed by RAs and RPAs acting within their scope of practice under state licensing laws.

CMS did clearly state that physicians **and** NPPs are permitted to provide direct supervision for Level 2 tests that require the proximity of being in the office suite and immediately available, but not in the room where the test is administered.

Conclusion

The bottom line is that the most recent rulemaking from CMS remains unclear on the authority of NPPs to supervise any diagnostic tests. It's possible that CMS made drafting errors in crafting the language in the Code of Federal Regulations. Or, despite the ambiguity in the drafting of the rule, the limited role of NPPs may have been intentional on the part of CMS.

Nevertheless, it is clear that changing circumstances in the delivery of testing services have sparked regulatory reform. Stakeholders in the imaging space will need to stay tuned to learn what CMS actually intended regarding how these services are to be performed. Given the potential for fraud and abuse scrutiny when tests are not supervised in total accord with Medicare rules, imaging providers and suppliers need to remain scrupulous in assuring adherence to a conservative interpretation of these rules until CMS provides further clarifications.

"Stakeholders in the imaging space will need to stay tuned to learn what CMS actually intended regarding how these services are to be performed."

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7th Annual Health Care Conference:
Health Care in a post-COVID world – October 19-22, 2020

Highlights from the Annual Health Care Conference

The pandemic has fundamentally changed the health care and life sciences industry. So what comes after COVID for organizations operating in this space? In our flagship health care conference, Reed Smith attorneys and industry experts explored that question in a series of thought-provoking sessions.

Want to watch a specific session of the 2020 conference on demand?

Visit our conference web page.

> “Expectation that post-COVID, there will be more flexibility to managing some depositions or government interviews remotely.”

In case you missed our 2020 conference, we’ve put together a rundown of the highlights.

Employees at work: What the health care industry needs to know

- Companies can be confronted with many legal issues and considerations when their employees return to work post-COVID, and must comply with DOL, EEOC and ADA guidance when asking employees to return.
- Once back to in-person work, employers can require employees to comply with COVID-related safety measures, including temperature screenings, mask-wearing and observation of infection-control practices.
- Companies should consider reviewing and updating health and safety policies before asking employees to return to the office to help mitigate legal exposures and risk.
- Employers need to consult with legal counsel to determine best practices in relation to the current state of advice and guidance on vaccines.

Virtual investigations during – and after – the pandemic

- Companies need to ensure they are getting the information needed to conduct internal investigations with the shift to remote work, and generating sufficient interaction with the compliance function when employees are not in the office.
- Remote witness interviews have introduced new technological considerations and risks, including the need for breakout rooms, data encryption, recording concerns, and employee access to necessary technology.
- Lawyers need to be mindful of protecting the attorney/client privilege, including maintaining the confidentiality of their conversations and considering how they share certain documents when the discussions are over a virtual platform.
- Expectation that post-COVID, there will be more flexibility to managing some depositions or government interviews remotely.

Compliance 2.0: Rethinking compliance in the modern age

- DOJ Compliance Guidance (Evaluation of Corporate Compliance Programs, updated June 2020) includes no significant structural changes, but represents government’s evolving and increasing expectations of the operations focus and analytic capabilities corporate compliance teams.
- In response, companies need to rethink and redesign their compliance programs, to focus staffing and tools on building the skill sets and capabilities to support a more intense focus on technology (data and systems) and processes (procedures and operations).
- DOJ’s expectation is that its investigation targets’ operations teams can produce data and reports that directly support or contradict its theories, and – because of that – emphasizes data-driven corporate compliance programs and analysis-driven risk identification and decision-making.

“The remote work environment creates additional technology competence considerations.”

D&O and E&O insurance challenges in a time of increasing cost and risk

- The D&O and E&O insurance market had been constricting since 2018, and the COVID D&O market resulted in an increased number of securities lawsuits and claims that has delayed the market correction we otherwise would have anticipated by this time.
- Policy holders need to carefully monitor enterprise risk, and understand what is not covered under the D&O (examples include Employment Practices Liability, Crime and Special Risk) and explore ways to use specialty insurance products, captive insurers, and other risk-mitigation vehicles to protect their company’s balance sheets and the personal assets of their directors and officers.
- The market can expect to see a continued increase in D&O claims based on disclosures, return to work risks, and employment issues.

Legal ethics in the age of COVID-19

- Law firms and in-house legal departments must ensure all relevant personnel are aware of the implications of remote work on compliance with various Rules of Professional Conduct, including Unauthorized Practice of Law, Competence, and Confidentiality of Information Rules.
- The remote work environment creates additional technology competence considerations, including risks and benefits of various remote technology platforms and devices, and the application of appropriate security measures to protect confidential communications and information.
- Protecting privilege in a remote work environment also introduces new risks and considerations, including proximity to family, friends and neighbors who can potentially hear conversations, less secure places to conduct privileged communications, and even personal voice assistants able to listen to conversations.

Telehealth blocking and tackling: How companies can manage the changing regulatory landscape/ Telehealth post-COVID-19 (A conversation with PlushCare Chief Medical Officer, Dr. James Wantuck)

- Telehealth market has grown significantly during the COVID-19 pandemic.
- Many states temporarily waived laws restricting telehealth, including state licensure, consent, and prior relationship requirements. Those waivers expire at varying times and under a variety of circumstances.
- Medicare and many state Medicaid programs have temporarily expanded telehealth coverage and eliminated related requirements.
- Several federal telehealth restrictions have been relaxed during the pandemic (fraud and abuse enforcement, data privacy and HIPAA requirements, etc.).
- It is unclear which telehealth changes, if any, will remain permanent after the public health emergency.
- More telehealth activity will invite scrutiny (e.g., audits, investigations, enforcement actions, payor disputes), requiring telehealth providers and related companies to enhance risk mitigation strategies going forward.


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