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UNLAWFUL, UNFAIR AND UNWISE: CONSTITUTIONAL AND RULEMAKING INFIRMITIES IN CMS's ENROLLMENT REVOCATION REGULATIONS AND HOW TO CHALLENGE THEM

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Welcome to the Medicare Program – Now Get Out

Imagine you are a physician who has been convicted of a minor felony, such as one count of possession of a controlled substance, which was not a crime of dishonesty or had anything to do with Medicare or any other healthcare program. You report the felony conviction to your Medicare contractor within 30 days, as required. You also report the conviction to the state licensing board, which decides to take no action against your license. You wait to see what happens with Medicare, because, after all, revocation of billing privileges for a felony conviction is not automatic. Revocation due to a felony conviction is supposed to be based on a determination that a provider's or supplier's continued participation in the Medicare program is "detrimental to the best interests of the Medicare program and its beneficiaries"[1] (whatever that means). Two years later, without any notice of a proposed revocation for which you would be offered the opportunity to respond, or any other warning from your Medicare contractor, you receive a notice stating your billing privileges are revoked for a period of three years. To make matters worse, the contractor notifies you that it is recouping Medicare payment for all of the services from the date of your conviction through the date of the notice, which amounts to several hundreds of thousands of dollars.

Or imagine that you are a physician practice that employs someone who is listed as a managing employee on the practice's enrollment form. The employee does not tell you that he has been excluded from participation in the federal healthcare programs by the Department of Health and Human Services' Office of Inspector General ("OIG") and despite your routine searches of OIG's listing of excluded individuals and entities ("LEIE") you fail to find that he has been excluded.[2] You discover he has been excluded when you receive a notice from the Centers for Medicare & Medicaid Services ("CMS") informing you that your billing privileges have been

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Chair's Corner

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revoked for three years for having an excluded individual as a managing employee.[3] Although CMS's regulations allow it to rescind a revocation where the provider or supplier fires the managing employee (or if is an owner who is the subject of the adverse action terminates the owner's ownership interest) within 30 days of the revocation,[4] and although you do so within a matter of days, CMS refuses to rescind the revocation. Instead, the revocation of billing privileges is made retroactive to the date of the employee's exclusion and an overpayment is created in the amount of $500,000.

Revocation actions like those in the above hypotheticals (which are based on actual revocations) are happening under the enrollment revocation regulations. This article looks at due process and other serious issues with how CMS's regulations are written and applied. It addresses the following questions:

- Do the regulations violate due process by not providing for a pre-revocation right to respond?
- Do the regulations violate due process by not providing fair notice that a provider or supplier may have its billing privileges revoked?
- Are the regulations arbitrary and capricious by not providing any guidance as to the length of the reenrollment bar that will apply in individual cases, and why does it seem that almost every revocation results in the maximum three-year reenrollment bar?
- Are the regulations unconstitutional or arbitrary and capricious by providing that the effective date of the revocation is retroactive to the date of the adverse action that formed the basis for the revocation?
- Is the appeals process needlessly unfair by not providing expedited judicial review as other Medicare appeals processes do and by prohibiting providers and suppliers from appealing the length of the reenrollment bar?
- Does CMS's reinterpretation of the regulations to provide for a reenrollment bar for certain deactivations (while still denying appeal rights for the deactivation determination) violate the rulemaking provisions of the Medicare Statute and the Administrative Procedure Act?
- Does CMS's delegation to contractors to make the revocation determinations a violation of the revocation regulations, and is CMS providing appropriate oversight of the contractors and providing adequate guidance to them and to providers and suppliers?
- Apart from the question of legal deficiencies, is CMS's revocation process unfair and create bad feelings among physicians and other suppliers, and is it unwise in light of the continuing physician shortage?

In addition to addressing the questions posed above, this article also provides some guidance for challenging revocation determinations prior to exhausting the administrative appeals process.

Constitutional Infirmities

Do the regulations violate due process by not providing for at least a pre-revocation right to respond?

In order to address this question, one must first consider whether an enrolled provider or supplier has a constitutionally-protected property or liberty interest in its continued participation in the Medicare program. There is some split of authority as to whether a protected property interest exists, but the case law seems to be squarely on the side of providers and suppliers as to whether a protected liberty interest can exist.

Is there a protected property interest?

In *Board of Regents of State Colleges et. al v. Roth*,[5] the Supreme Court clarified that determining whether someone has a property interest depends on whether there is a reasonable expectation of a continued receipt of a benefit. Such expectation must be "more than [] unilateral" and "more than an abstract need or desire" and, instead, must be "a legitimate claim of entitlement to it."[6] The Court explained that property interests are not created by the Constitution, but rather, "they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law – rules or understandings that secure certain benefits and that support claims of entitlement to those benefits."[7] Under this test, wherever there are standards that bind a state or federal agency that must be followed before entitlement or benefits can be taken away, there is a protected property interest. Because providers and suppliers can have their billing privileges revoked only for the reasons specified under the revocation regulations, proper application of *Roth* leads to the conclusion that they have a protected property interest in maintaining their ability to bill Medicare.

However, there is an apparent split of authority as to whether there is a protected property interest in the continued participation in Medicare When one considers the precise issue – a property interest in the continued enrollment in Medicare – and the fact that the enrollment regulations provide specific criteria that ostensibly are binding on both CMS and the providers/suppliers, *Roth* instructs that there is a protected property

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interest and more courts than not have agreed.[8]

Decisions by and within the Second Circuit are instructive in this regard. In *Case v. Weinberger*,[9] the court stated it was clear that the operator of a nursing facility had a property interest in her expectation of continued participation in the Medicaid program. In *Patchogue Nursing Center v. Bowen*,[10] the Second Circuit stated, in dicta, that "health care providers have a constitutionally protected property interest in continued participation in the Medicare and Medicaid programs. . . ."[11] Subsequently, in *Plaza Health Laboratories v. Perales*[12] the Second Circuit noted that "the combination of rights reserved by the State with regard to Medicaid providers…casts doubt on whether the provider's interest in continuing as a provider, either indefinitely or for any period without interruption, is a property right that is protected by due process."[13] However, the court also stated that "[w]here the state provisions bestow a right that cannot properly be eliminated except for cause, that right constitutes property protected by procedural due process."[14] This language was quoted with approval by the Second Circuit in *Senape v. Constantino*.[15] In *Furlong v. Shalala*,[16] the Second Circuit applied the principle that a constitutionally protected property interest exists where rules circumscribe the exercise of discretion by a Medicare contractor. Specifically, the court held that the constant, consistent pattern of administrative law judge ("ALJ") decisions on a payment issue was sufficient to create a property interest in the receipt of Medicare payments.[17]

The Fourth Circuit's assertion in *Ram v. Heckler*[18] that the "expectation of continued participation in the Medicare program is a property interest protected by the due process clause of the fifth amendment"[19] also appears rooted in the lack of complete discretion of the granting authority. The court made this statement without discussion, and simply cited its earlier decision of *Bowens v. North Carolina*.[20] In *Bowens*, the court concluded that the provider's participation in Medicaid was not terminable at will based on the state regulations' procedural requirements, which included a peer review process. The court held that "the regulations create a property interest in continued participation in the program unless terminated for cause."[21]

In *Robie v. Price*,[22] the district court said that "the courts are in agreement that due process does not entitle a physician to a full evidentiary hearing prior to having his Medicare billing privileges revoked," but, quoting *Mathews v. Eldridge*, noted that "[t]he fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.'"[23] Employing the three-part balancing test in *Eldridge*, and under the facts before it, the court held that the physician was entitled to an in-person meeting before his billing privileges could be revoked.[24]

In *Ritter v. Cohen*,[25] the Third Circuit indicated in dicta that where the agency official's discretion is constrained, a provider has a property interest in the continued participation in the State's Medicaid program.[26]

There is no D.C. Circuit opinion on point, but in *ABA, Inc. v. D.C.*,[27] the district court held that the plaintiff home health agencies had "a viable property interest, protected by due process, that [the D.C. Medicaid agency] could not terminate without prior notice and hearing."

In contrast, the First, Tenth and Ninth Circuits have found that there is no property interest in the continued participation in the Medicare program. In *Cervoni v. Sec'y of Health, Ed. and Welfare*,[28] the First Circuit concluded that physicians do not have a protectable property interest in continuing eligibility under Medicare part B, reasoning that "the real parties in interest are the beneficiaries; physicians are parties in interest only as assignees of the beneficiaries." In *Koerpel v. Heckler*,[29] the Tenth Circuit found that a physician who was challenging his exclusion from participation in federal healthcare programs by the OIG did not have a protected property interest because he had only a "reimbursement expectation, and that "no clear promises have been made by the Government."[30] The Ninth Circuit *in Erickson v. U.S. Dept. of HHS*[31] stated that it was following the First and Tenth Circuits in reaching its conclusion that "plaintiffs do not possess a property interest in continued participation in Medicare, Medicaid, or the federally-funded state health care programs."[32]

To say that providers and suppliers are not the "intended beneficiaries" of the Medicare program offers very little in the way of analysis. In particular, the idea that one must be the intended beneficiary of a federal program is at odds with the rule espoused in *Roth* that, where there are standards that bind a state or federal agency that must be followed before entitlement or benefits can be taken away, there is a protected property interest. In other words, the fact that a person may not be the *primary* intended beneficiary of a program does not mean that the program does not create rights and obligations for that person. In this regard, it is interesting to compare the Tenth Circuit's decision in *Koerpel v. Heckler* with its earlier decision, *Geriatrics Inc. v. Harris*,[33] which was relied upon in *Koerpel*.[34] In *Geriatrics Inc.*, after the court noted the plaintiff's argument that, under *Roth*, it had more than a unilateral claim or mere expectancy, it said that a protectable property

interest must be an interest secured by statute or legal rule or through a mutually explicit understanding. It then said that the regulations in effect at that time required the Secretary of Health and Human Services ("Secretary") to inform a nursing facility that its agreement would not be renewed and to state the reasons for non-renewal, and also provided administrative appeal rights. According to the court, these provisions taken alone may have appeared to create an expectation between government and facility of renewal, but that when the entire regulatory scheme was considered there was no basis for such an expectation. In particular, the court emphasized that (at that time) federal law limited provider agreements to a year, and the provider was required to be surveyed each year and reapply each year to continue participating in the Medicare program.[35] This automatic termination scheme is obviously different from the enrollment regulatory scheme whereby there are specific standards (such as they are) that must be applied to revoke one's billing privileges.

In *Nawaz v. Price*,[36] the district court held that the plaintiff physicians whose billing privileges were revoked could not show that they held a protected property interest in their continued participation in the Medicare program, but did so without analysis or without citation of authority. In another district court case, *Fayad v. Sebelius*,[37] the court's holding was that a physician who had his Medicare billing privileges revoked was not entitled to a pre-revocation hearing. That in itself is hardly controversial, because, as noted above, a pre-termination hearing or a pre-revocation hearing would be unusual relief. However, the court also voiced its agreement with the Secretary that after-the-fact appeal rights provide "adequate protection."[38] The court did not address a pre-revocation right to respond that falls short of an evidentiary hearing (perhaps because it does not appear from the opinion that the plaintiff sought one), and did not recognize in its opinion the narrow scope of review in the administrative appeals system as opposed to what may be raised in a judicial proceeding contesting a revocation.[39]

Is there a liberty interest?

Most courts that have considered the issue have decided that there can be a protected liberty interest in a provider's or supplier's continued participation in the Medicare program. In *Erickson v. U.S. Dept. of HHS*,[40] after concluding that the excluded physician did not have a protected property interest, the Ninth Circuit decided that he did have a protected liberty interest. The court began by citing previous Ninth Circuit precedent and *Roth* for the proposition that a person's liberty interest is implicated if a charge impairs his reputation for honesty or morality.[41] The court held that the procedural protections of due process apply if the accuracy of the charge is contested, there is some public disclosure of the charge ("publication"), and it is made in connection with the termination of employment or the alteration of some right or status recognized by law.[42] Those requirements were met, according to the court. *See also Trifax Corp. v. District of Columbia*, in which the D.C. Circuit stated that formally debarring an entity from bidding on government contracts would have unquestionably constituted a deprivation of liberty.[43]

In comparison, in *Sudderth v. Shalala*,[44] the district court, in rejecting an excluded physician's claim of a protected liberty interest. described Ninth Circuit precedent as "interesting but not persuasive" and noted that "[n]o Fifth Circuit authority exists for the proposition that physicians have a protectable liberty interest in their status as participating health care providers under Medicare." In *Arriva Med. LLC v. US HHS*,[45] Arriva, a supplier of diabetic-testing equipment was informed by CMS that it was revoking the company's billing privileges. In this case, the Secretary conceded that Arriva had a liberty or property interest in its billing privileges. Yet the Court noted that "the private interest at stake is not particularly strong because the Medicare provider is not the intended beneficiary of the Medicare program."[46]

The Office of Inspector General (OIG) gives a pre-exclusion right to respond

Any argument the Secretary would proffer that due process does not require a pre-revocation right to respond is undercut by his position on exclusions. In contrast to revocations of billing privileges, OIG-imposed permissive exclusions from federal healthcare programs are preceded by a pre-deprivation right to respond. Although the OIG does not provide for a pre-exclusion *hearing* (except in limited situations) in promulgating its regulatory exclusion procedures, it recognized that an opportunity to provide some type of pre-exclusion *response* was mandated by due process.[47] In doing so, the OIG explained that it was the opportunity to respond that was essential as a matter of Constitutional right:

> As we stated in the preamble to the proposed regulations, case law makes clear that due process does not require a *hearing* prior to the imposition of an exclusion from Medicare or State health care programs (*see Mathews v. Eldridge*, 424 U.S. 319 (1976); [citation omitted]. **When an agency exercises discretionary authority, due process is satisfied so long as the affected party is given "notice and an opportunity to respond * * * (t)he opportunity to present reasons, either in person or in writing, why proposed action should not be taken"** (*see Cleveland Bd. of Education v. Loudermill*, 470 U.S. 532, 105 S.Ct. 1487, 1495 (1985)). **This final rule reflects this constitutional principle.**[48]

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Given the Secretary's apparent belief that due process requires an opportunity to respond prior to the imposition of a discretionary proposed exclusion, it is inconsistent for the Secretary to believe that due process does not require an opportunity to respond prior to imposing a discretionary revocation of billing privileges based on a felony conviction. A revocation of Medicare billing privileges, which requires Medicaid also to revoke Medicaid billing privileges,[49] is the functional equivalent of an exclusion. In either case, the multi-year prohibition on billing Medicare and Medicaid is the death knell for any provider or supplier that has any significant degree of Medicare and Medicaid business.

It should also be noted that, as a general rule, CMS gives prior notice with an opportunity for rebuttal for a proposed suspension of payment, recoupment of an assessed overpayment, or offset. The rebuttal allows a provider or supplier to submit a statement as to why a suspension of payment, offset, or recoupment should not be put into effect, or why a suspension should be terminated. CMS or its contractor must, within 15 days from the date the rebuttal statement is received, consider the statement (including any pertinent evidence submitted), together with any other material bearing upon the case, and determine whether the facts justify the suspension, offset, or recoupment or, if already initiated, justify the termination of the suspension, offset, or recoupment.[50] If a provider or supplier has an opportunity to submit a rebuttal statement with evidence prior to an overpayment (which could be for a relatively minor amount) or prior to a temporary suspension of payments, why is there not a right for the provider or supplier to a pre-revocation right to respond when it is faced with the loss of all Medicare (and Medicaid) income for a period of years?

Due process and retroactive revocations

The due process discussion above has focused on prospective revocations, i.e., the contractor or CMS sends a notice stating that the provider's or supplier's billing privileges are revoked, and the revocation becomes effective 30 days from the date of the notice.[51] However, as discussed in detail below, for certain revocations the effective date is retroactive to the event that served as the basis for the revocation, and an overpayment is assessed with respect to all Medicare services that were furnished and paid with dates of service from the date of the precipitating event through the date of the notice of revocation. For example, if the contractor sends a revocation notice on September 1 that a supplier was non-operational as of the preceding January 1, it will revoke billing privileges back to January 1 and create an overpayment for the period January 1 – September 1.[52] Like every other revocation, however, revocations that carry retroactive effect are made with no opportunity for a pre-revocation right to respond. Whatever debate there can be as to whether a provider or supplier has a protected property interest in the continued participation in the Medicare program is beside the point with respect to the recoupment of funds that were already paid to that provider or supplier. As noted above, and in recognition of the constitutional protection that one cannot be deprived of property without due process, the regulations do give a provider or supplier that has received a notice of an overpayment the right to submit a rebuttal statement as to why offset or recoupment of the alleged overpayment should not be put into effect; however, this rebuttal statement does not afford the provider or supplier the opportunity to explain why the revocation of billing privileges was in error. Instead the adjudicator will simply look to see if there is a regulatory basis for the overpayment, which in turn simply involves checking to see that the revocation was one for which the regulations give retroactive effect. Thus the lack of due process is even more pronounced in the situation of a retroactive revocation.

As discussed below, the regulation providing for retroactive terminations is susceptible to challenge in the courts.

The value of a pre-revocation right to respond

An important reason why a pre-deprivation right to respond is necessary has to do with the emotional investment by an agency official and his or her superiors who will circle the wagons after a final determination has been made and challenged. If an agency has made a preliminary determination that 2 + 2 = 5, and the determination is characterized as tentative and preliminary, so that the agency can save face if it changes its mind, there is a better chance of convincing the agency that the correct answer is 4, as opposed to where the agency has made a final determination, without seeking input that the answer is 5. In addition, the ability to respond pre-revocation is especially important given the length of the administrative appeals process,[53] and the lack of authority for the administrative appeals adjudicators to rule on any challenges to regulations.[54] The length of the appeals process is also exacerbated by the lack of any expedited judicial review process to get challenges to the regulations or constitutional issues in front of a court without wasting time and money in the administrative appeals process.[55]

Also, the length of the administrative appeals process is aggravated by the ability of the agency to reset the clock. It is not infrequent that a

revocation will be issued, the provider or supplier appeals from it and points out certain errors, and CMS or the contractor will then issue a revised revocation determination, from which the provider or supplier must seek reconsideration. The time for issuing a reconsideration determination on the appeal of the revised revocation determination is not abbreviated based on the fact that the provider or supplier already appealed the original revocation determination.[56] In short, apart from the Constitutional infirmities, not giving a pre-revocation right to respond is poor policy.

Do the regulations violate due process for not providing adequate notice that a provider or supplier may have its billing privileges revoked, for not providing adequate notice of the reason for why billing privileges were revoked, and for not providing adequate notice as to the length of the enrollment bar?

It is a bedrock principle of due process that statutes and regulations that govern conduct are required to give fair, adequate notice or warning of what they command and prohibit.[57] As the Supreme Court stated:

> A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required. [A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law....This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment. . . . A conviction or punishment fails to comply with due process if the statute or regulation under which it is obtained fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement.[58]

The void for vagueness doctrine serves important interests:

> First, because man is free to steer between lawful and unlawful conduct, laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning. Second, if arbitrary and discriminatory enforcement is to be prevented, laws must provide explicit standards for those who apply them. A vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application.[59]

There are two basic problems with CMS's revocation regulations in this regard. First, with the exceptions of paragraphs (a)(3) (felony convictions), (a)(8) (abuse of billing privileges), and (a)(14) (improper prescribing practices) there are no prescribed standards in section 424.535 to guide the discretion of the adjudicator and put the provider or supplier on fair notice that it may have its billing privileges revoked. Congress did not give CMS the authority to revoke billing privileges through a standardless, unfettered exercise of discretion.[60] Second, the standard for revoking billing privileges due to a felony conviction (continued participation is "detrimental to the bests interests of the Medicare program and its beneficiaries") is impermissibly vague in the absence of regulations that put skin on the bones.

Whereas CMS may not be able to publish standards or guidelines that operate with absolute precision, it violates fair notice requirements to have such an amorphous standard as "against the best interests of the Medicare program and its beneficiaries" with not even a listing – even a non-exclusive listing – of the factors CMS will consider, let alone whether any factor will be determinative, and how much weight will be given to any factor. For example, CMS could let providers and suppliers know whether and the extent to which the following factors are taken into account: whether the conviction resulted in imprisonment versus probation; whether the provider or supplier had any history of fraudulent or abusive billing or instead had a clean billing history; whether the conviction related in any way to the delivery of healthcare; whether and to what extent it matters that the conviction does or does not involve a financial crime; whether the conviction is related in any way to any patient abuse or a crime involving financial or other harm to a patient; and whether the provider or supplier had any previous conviction of a misdemeanor or felony. It is especially egregious not to provide any clue as to what is against the best interest of the Medicare program and its beneficiaries where the effective date of the revocation is retroactive and operates to create an overpayment for necessary services that were furnished appropriately and in good faith.

Finally, the regulations provide that the length of reenrollment bar chosen in any given case by CMS depends on the severity of the basis of the revocation,[61] but the regulations do not explain how severity is measured, and the written revocation determinations almost never or never explain how severity was measured in the provider's or supplier's particular circumstances. Moreover, although the regulations state that the length of the reenrollment bar is a minimum of one and a maximum of three years,[62] thereby allowing CMS to impose an enrollment bar for any

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period between one and three years (e.g., 15 months), in practice the length of the enrollment bar is always one, two or three years (and most often three years).

Rulemaking Issues

Are the regulations arbitrary and capricious by not providing a pre-revocation right to respond to a proposed revocation?

One does not know to what extent, if at all, the Secretary believes that due process does not require a pre-revocation right to respond because there is virtually no discussion of due process and a pre-revocation right to respond in the enrollment rulemakings. Nor is there any discussion as to why, as a policy matter, providing a pre-revocation right to respond would or would not be advantageous when weighing the risk of erroneous deprivation (with its attendant costs of appeal and other financial and non-financial costs) versus whatever costs would be incurred by providing a right to respond. Thus, in terms of rulemaking procedures, there was no proposal to require or not require a right to respond before a revocation becomes final. As far as one can tell, the issue was simply not considered.

Are the regulations procedurally and/or substantively deficient by providing that the effective date of some revocations is retroactive to the date of the adverse action that formed the basis for the revocation?

Section 424.535(g) provides that where the revocation is based on a felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation, or the date that CMS or its contractor determined that the provider or supplier was no longer operational. This means that the precipitating event for the revocation (e.g., a felony conviction) may happen months or years prior to the notice of the revocation, yet the revocation will be effective back to the date of the precipitating event. Worse, a provider or supplier may have its billing privileges revoked because it has employed someone, or has as one of its owners someone who has been excluded or has had a felony conviction,[63] and if it does have its billing privileges revoked, the revocation will be retroactive to the date of the exclusion or felony conviction.[64]

Because the practical effect of having one's billing privileges revoked is that one cannot be paid by Medicare for services furnished during the period of revocation (unless the revocation is reversed on appeal), that means that months or years after the precipitating event the provider or supplier may receive notice that its billing privileges are revoked retroactive to the date of the precipitating event, and that it must repay a huge overpayment. This result could make sense if *both* of the following are true: (1) revocations are made retroactive only to the date of the provider's or supplier's required reporting to CMS of the precipitating event; (2) revocations for the above precipitating events are mandatory. But both (1) and (2) are not true, and in fact neither (1) nor (2) is true. Retroactive revocations are made irrespective of whether the provider or supplier timely has given notice of the precipitating event (and are not retroactive only to the date of the notice of the precipitating event). And of course, *all* revocations are (or at least they are supposed to be) discretionary and not mandated, so a provider or supplier will not know at the time of the precipitating event that its billing privileges will be revoked sometime in the future. In fact, not only will a provider or supplier not know that its billing privileges will be revoked at the time of the precipitating event, but, as discussed above, it will have either no standards, or at most amorphous standards, in the regulations that it can look to for taking an educated guess as to whether its billing privileges will be revoked.

Therefore, as noted at the outset of this article, a physician or other supplier or provider could rack up an overpayment of hundreds of thousands of dollars (or more) for reasonable and necessary and otherwise proper services that were furnished between the time of the precipitating event and the notice of revocation. There does not appear to be any legitimate purpose for this policy, but rather its design (or at the very least its effect) is to coerce providers and suppliers into leaving the Medicare program following the precipitating event to avoid a potentially crushing overpayment or, if the provider or supplier does not leave the program and continues to furnish covered services after the precipitating event and bill Medicare for them, to effectuate a windfall for CMS.

The retroactive revocation provision of section 424.535(g) was finalized in the Calendar Year ("CY") 2009 Physician Fee Schedule ("PFS") final rule.[65] The CY 2009 PFS proposed rule proposed regulations text (in section 424.535(f)) that tracks the current language in section 424.535(g), but the preamble discussion arguably did not put physicians and other practitioners on adequate notice that CMS could finalize a rule whereby every revocation based on an adverse action would be made retroactive to the date of such action and an overpayment created for services furnished from that date – regardless of whether the action was reported

timely. Moreover, what little preamble discussion there was concerning the proposed regulations text seems to have proceeded from a non-sequitur, namely, that CMS' concern that providers and suppliers were not incentivized to report adverse actions timely needed to be addressed through retroactive revocations.

The preamble discussion in the CY 2009 PFS proposed rule focuses on the need to report adverse events timely, and used the threat of revocation as a means of incentivizing providers and suppliers to report those events timely. This is very different from proposing to make retroactive revocations simply due to the adverse events and irrespective of whether the adverse events are reported timely. Under the heading "Reporting Requirements for Providers and Suppliers (proposed § 424.516 and § 424.535(a)(10))" the proposed rule posited that, while physicians and other practitioners were required to report changes in their enrollment profile within 90 days of the reportable event, in many cases there was little or no incentive for them to report a change that could adversely affect their ability to continue to receive Medicare payments:

> For example, physician and NPP [non-physician practitioner] organizations and individual practitioners purposely may fail to report a felony conviction or other adverse legal action, such as a revocation or suspension of a license to a provider of health care by any State licensing authority, or a revocation or suspension of accreditation, because reporting this action may result in the revocation of their Medicare billing privileges. Thus, unless CMS or our designated contractor becomes aware of the conviction or adverse legal action through other means, the change may never be reported by a physician and NPP organization or individual practitioner. Alternatively, if CMS or our designated contractor becomes aware of the conviction or adverse legal action after the fact, we lack the regulatory authority to collect overpayments for the period in which the physician and NPP organizations and individual practitioners should have had their billing privileges revoked.[66]

From this premise, CMS proposed to require all physician and non-physician practitioner entities to notify their designated enrollment contractor of any adverse legal action within 30 days, and proposed that failure to do so could result in the revocation of Medicare billing privileges and a Medicare overpayment from the date of the reportable change:

> We believe that it is essential that this type of change be reported in a timely manner (that is within 30 days). For example, if CMS or our designated contractor determines in February 2008 that a physician failed to notify Medicare about an adverse legal action that occurred on June 30, 2007, that physician may be subject to an overpayment for all Medicare payments beginning June 30, 2007 and have its Medicare billing privileges revoked effective retroactively back to June 30, 2007 as well.
>
> Additionally, we are proposing to add a requirement for change in location at § 424.516(d)(1)(iii). Since a change in location may impact the amount of payment for services rendered by placing the physician and NPP organizations and individual practitioners into a new [Core-Based Statistical Area]. We believe that it is essential that physician and NPP organizations and individual practitioners report changes in practice location including those that impact the amount of payments they receive within a timely period (that is, 30 days). . . . Accordingly, we believe that failing to report changes in practice location would result in an overpayment for the difference in payment rates retroactive to the date the change in practice location occurred and may result in the revocation of Medicare billing privileges. . . .We believe that reporting these types of changes is essential for making correct and appropriate payments.
>
> Since it is essential that physician and NPP organizations and individual practitioners notify their designated contractor of these types of reportable events in a timely manner and to ensure that the provider or supplier continues to be eligible for payment, we believe that it is essential that we establish an overpayment from the time of the reportable event. We believe that establishing an overpayment and revocation of billing privileges for noncompliance from the time of the reportable event would provide the supplier with a compelling incentive to report reportable changes in the 30-day reporting period.
>
> In addition, if CMS or our designated contractor determines that a physician and NPP organization or an individual practitioner has moved *and has not reported the reportable event within the 30-day reporting period,* CMS or our designated contractor would impose an overpayment, if applicable, and revoke billing privileges for a period of not less than one year.[67]

To make matters worse in terms of not putting the public on notice that revocations due to adverse actions would be made retroactive and why, the proposed rule's discussion under the heading "Revocation of Enrollment and Billing Privileges in the Medicare Program (proposed § 424.535(g))," pertained only to a proposal to limit the claims submission timeframe after revocation:

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> In § 424.535(g), we are proposing that revoked physician and NPP organizations and individual practitioners, including physicians and NPPs, must submit all outstanding claims not previously submitted within 30 calendar days of the revocation effective date.[68]

Again, there is no language to put interested parties on notice that CMS might finalize a rule providing that every revocation based on an adverse action would be given retroactive effect and an overpayment created for services furnished from that date, irrespective of whether the action was reported timely. It is noteworthy that although CMS received many comments on the enrollment provisions in the proposed rule, apparently just about no one commented on the retroactive revocation provision as the final rule lists only one comment (to which CMS gave a non-responsive response).[69]

Instead, the only mention in the preamble of a proposal to make revocations based on an adverse action appears in a section of the proposed rule dealing with appeals of revocations. There is no rationale set forth there for extending the retroactive effect of revocations beyond situations in which the adverse action is not reported timely to CMS; rather, there is merely the statement that section 405.874(b)(2) (pertaining to appeals) would be revised to state "[w]hen a revocation is based on an exclusion or debarment, Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational." The preamble then states that in order to ensure consistency, section 424.535(f) would be revised to contain the same language quoted above.[70]

The lack of any real proposal to make revocations retroactive to the date of an adverse event irrespective of whether the provider or supplier reports the adverse event timely makes the regulation susceptible to challenge as procedurally deficient.

The regulation is also susceptible to challenge as being substantively invalid (arbitrary and capricious) for lack of any cogent explanation for the policy.

In the CY 2009 PFS final rule, CMS finalized the draft language for section 424.535(f) and moved it to 424.535(g). The final rule's discussion of the change is devoid of any real explanation. Twice it states that the rule change was intended to "ensure that Medicare is not making or continuing to make payments to providers and suppliers who are no longer eligible to receive payments."[71] This is a non-sequitur. Subject to limited exceptions, unless and until their billing privileges are revoked, providers and suppliers *are* eligible to receive Medicare payments following a felony conviction, or license or suspension or revocation, or following a determination of not operational.[72] The only logical explanations that come to mind for the language "who are no longer eligible to receive payments" are that the drafter (and the agency reviewers) (1) did not understand that adverse actions (with the exception of exclusions) do not by themselves prevent payment by Medicare, or (2) did not understand that all revocations are supposed to be discretionary. A third, more cynical explanation is that the purported discretionary nature of at least some revocations is a sham.

Are revocations habitually arbitrary and capricious for not explaining the basis for the revocation determination?

It is axiomatic that an agency adjudication must contain an adequate explanation for the action taken in order to survive an arbitrary and capricious challenge, yet CMS requires very little from its contractors with respect to their revocation letters. For potential revocations due to a pattern or practice of submitting incorrect claims, the regulations contain a list of weighting factors that guide the determination of whether to revoke.[73] Despite the regulations text that says that CMS shall consider these weighting factors when making the determination of whether to revoke, and provides a list of factors CMS considers when making the determination that a provider or supplier has a pattern or practice of submitting incorrect claims, the revocation notices do not explain how each of these factors entered into the revocation determination, or even state whether they were in fact considered[74] – this, despite CMS's assurance that it "cannot be stressed enough" that an (a)(8)(ii) revocation will be made "only after the most careful and thorough consideration of the relevant factors."[75]

Does imposing gaps in billing privileges upon a reactivation of a deactivated number violate rulemaking authorities?

CMS established the concept of deactivations in a 2006 final rule devoted solely to enrollment issues.[76] The 2006 final rule does not indicate that there would be a gap in billing privileges. Indeed, the preambles to that rule and various others contain statements that indicate that upon reactivation, a preceding deactivation would have no adverse effect on the provider or supplier.[77] The 2006 final rule defined "deactivate" as "mean[ing] that the provider or supplier's billing privileges were stopped, but can be restored upon the submission of

updated information," and that same definition continues to appear in the regulations.[78] The plain, dictionary meaning of "restored" means that something is put back as it formerly was.[79] As applied here, the definition of "deactivate" in the regulations means there is no gap in billing privileges. It is precisely because a deactivation does not have an adverse effect under the regulations that there is no regulatory right to appeal the deactivation itself. Moreover, when one considers that originally revocations did not result in a reenrollment bar, but rather imposed a gap period between the time of revocation and the effective date of a new application, there would have been no need for CMS to come up with the concept of a deactivation if there was no difference between a deactivation and a revocation. For these reasons, not surprisingly, manual instructions issued following the 2006 final rule made clear that a deactivation followed by a reactivation did not result in a gap in billing privileges.[80]

Notwithstanding the above, however, CMS changed its manual instructions – without changing its regulations – to provide for a gap in billing privileges. CMS directs its contractors to impose a "gap in coverage (between the deactivation and reactivation of billing privileges)" and to deny claims with dates of services falling within the gap period.[81] The regulations have not been changed and continue to define "deactivate" as noted above, and continue to deny appeal rights for deactivations. Therefore, if a provider or supplier contends that it did not receive the request for revalidation it will not be able to appeal the deactivation, although it is given a right to submit a rebuttal. Note that the requests for revalidations are not sent by certified mail or other means that evidences actual receipt. In other situations, CMS will send notice of a pending sanction through a mechanism that tracks actual receipt, not merely presumed receipt.[82]

CMS defends its reinterpretation on the basis of the language in section 424.520(d) of the regulations, which was added by a 2008 final rule,[83] and which states that the effective date for billing privileges for physicians and certain other suppliers is the later of the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor, or the date that the supplier first began furnishing services at a new practice location. However, this language was added following CMS's proposal to develop an effective date for *initial* enrollment applications – not applications following a deactivation.[84] The final rule does not indicate that section 424.520(d) was intended to have any effect on the effective date of billing privileges following a deactivation/reactivation, and in fact deactivations are not mentioned once in the 2008 final rule, or in the proposed rule that preceded it.[85]

CMS also defends its position on the basis of section 424.555(b), but this regulation simply provides that payment cannot be made to a provider or supplier *while the revocation or deactivation is in effect*.[86] It does not say, and it would make no sense for it to say, that if the revocation is reversed or the deactivation is followed by a reactivation the provider or supplier cannot now be paid for items or services that were furnished during the period of revocation or deactivation. By CMS's rationale, the revocation appeals process would be a farce – a provider or supplier that successfully appealed a revocation (and the time to finish the appeal could take longer than the reenrollment bar) would be left with no ability to bill for services it furnished on dates that were covered by the revocation period.[87] Although one ALJ has consistently found that CMS's reinterpretation is invalid because it is contrary to the plain meaning of the regulations,[88] the Department Appeals Board ("DAB") has repeated CMS's flawed arguments based on sections 424.520(d) and 424.555(b).[89]

Is the potential to submit a corrective action plan ("CAP") unduly restricted?

CMS allows CAPs (a/k/a plans of correction) only if the revocation was pursuant to section 424.535(a)(1) (noncompliance with enrollment requirements). CMS's explanation in the December 2014 final rule as to why it has restricted CAPs to only (a)(1) revocations, i.e., because the other grounds can be more serious, is unpersuasive at best.[90] There does not seem to be a good reason for not evaluating whether to accept a CAP on a case by case basis, as there can be extenuating circumstances regardless of the grounds for revocation, and if the purpose of revoking one's billing privileges is to protect the program and its beneficiaries, instead of doling out punishment even for mistakes, it seems CMS should consider whether a provider or supplier can provide reasonable assurances that it will be in full compliance with all requirements going forward. Although the CAP process is modeled on that in Part 488 of the regulations ("Survey, Certification and Enforcement Procedures"), the availability of CAPs for the termination of provider agreements for nursing homes and other providers is not restricted to certain grounds for terminations. Indeed, the regulations provide that CAPs are available even in immediate jeopardy situations.[91] In fact, the approach in the survey and certification process for providers and suppliers is to terminate the provider or supplier agreement only as a last resort – after giving the provider or supplier an opportunity to submit a CAP. This is in stark contrast to the revocation process, which seems to be designed or at least implemented for the purpose of revoking billing privileges as the first and only resort. This might be excused if the period of revocation was exceedingly brief, but it is not. As noted above, revocations are for either one, two or three years (and nothing in between), and it seems

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that the great majority are for three years. Moreover, some revocations are applied retroactively so as to create an overpayment for services that were furnished during the period prior to the revocation notice. In contrast, a provider or supplier that has had its agreement terminated can come back into the Medicare program as soon as it is surveyed and meets all federal requirements. Admittedly, a survey can take several months, but that is a far cry from three years.

The stingy approach to CAPs in the revocation process encapsulates the lack of fairness that is pervasive throughout the revocation regulations. Take for example the case of a physician who moved from a foreign country to set up practice in the United States, and specifically to see homebound patients in their homes and in assisted living facilities. Knowing that she was unfamiliar with the Medicare enrollment system, the physician engaged a consultant to assist her in her enrollment. The consultant may have given her inaccurate advice, and in any event, she did not list all of the addresses where she saw patients, and one address listed was where she received correspondence and not where she saw patients. One would think that given these facts, CMS would view this as a foot fault by someone who was new to the country, who was providing a valuable service by seeing homebound patients, and tried to do the right thing by hiring a supposed expert, but no. The physician attempted to submit a CAP, but CMS refused to consider it and revoked her billing privileges for two years.[92]

Is the appeals process unduly cumbersome and restrictive?

The Part 498 appeals process (so-called because it appears in Part 498 of 42 C.F.R.) is the means for appealing revocations. The fundamental problem with the appeals process is that, on the one hand, appellants must complete the process before going to court, but on the other hand, the appellate adjudicators are without authority to declare a regulation invalid. Moreover, CMS takes the position that, although one can appeal the revocation itself, one cannot appeal the length of the revocation.[93] This is particularly unfair because, unlike the situation with challenges to regulations whereby CMS cannot give appellate adjudicators the authority to depart from them, there is no reason why CMS cannot extend appeal rights to determinations as to the length of the reenrollment bar,[94] and no reason why providers and suppliers should not be able to argue that the contractor abused its discretion in setting the length of the reenrollment bar.[95] The regulations provide that the length of the reenrollment bar depends on the severity of the basis for the revocation,[96] but it seems that the great majority of the revocations are for a period of three years, and the revocation determinations rarely if ever provide any explanation as to why one period was chosen over another.

The problem with the narrowness of the adjudicators' review authority is exacerbated by the length of time it takes to complete the appeals process for revocations, coupled with the lack of an expedited judicial review ("EJR") process. In contrast, the multi-level coverage/claims appeals process has an EJR process, through which the claimant can request EJR at the ALJ or the DAB and proceed directly to court.[97] The request must assert that the only factor precluding a decision favorable to the requestor is a statutory provision that is unconstitutional, or a provision of a regulation, national coverage determination, or CMS Ruling (all of which are binding on the ALJ and the DAB) that the requester considers invalid.[98] Likewise, the Provider Reimbursement Review Board ("PRRB") appeals process contains an EJR process (mandated by statute) by which the PRRB can grant EJR on the basis that the provider has alleged that the only factor preventing it relief is a statute that it considers unconstitutional or a regulation or a CMS Ruling that the provider believes is invalid.[99]

The reason for requiring exhaustion of administrative appeal rights – that the agency should be given a chance to correct its own errors – simply does not pertain where the appeals adjudicators lack the authority to grant relief. Of course, there will be cases where the provider or supplier has arguments that the appeals adjudicators can rule on as well as those for which the appeals adjudicators cannot, and in those cases, if the provider or supplier wishes to raise both types of arguments on appeal, it would be appropriate for CMS to preclude EJR.[100] However, where the only issues the provider or supplier wish to bring on appeal are ones that can be decided only by the courts, there is no reason to put appellants through the waste of time and expense of going through an appeals process that will not offer relief. Indeed, with no income from Medicare, and perhaps Medicaid as well, the provider or supplier may be out of business before it can complete the process.[101]

In addition to the problem of ALJs and the DAB not having the authority to declare regulations invalid is the reluctance of the ALJs and the DAB to exercise the authority that they do have, as discussed immediately below.

Contractors are not permitted to make revocation determinations, but they do so anyway and CMS does not seem to care

Section 424.535(a) states "CMS may revoke a currently enrolled provider or supplier's Medicare billing

privileges and any corresponding provider agreement or supplier agreement for the following reasons." Thus the plain language of the regulations states that it is CMS and not the contractor that makes all revocation determinations. Moreover, there are other places in section 424.535 that state that CMS will make the revocation determination.[102] Nowhere in section 424.535 does it state that contractors are permitted to make any revocation determination. In explaining why CMS and not its contractors makes the determination that a provider or supplier should have its billing privileges revoked because of a pattern or practice of submitting incorrect claims, CMS stated repeatedly that it, and not its contractors, would make that determination.[103]

Notwithstanding the plain language of the regulations, however, CMS routinely permits its contractors to make the revocation determination. In *Fayad v. Sebelius*[104] the court held that the Social Security Act gives the Secretary authority to delegate functions to contractors, including the responsibility to make revocation determinations. However, from the opinion's description of the facts, apparently the plaintiff did not argue that the plain language of the regulations requires CMS to make the revocation determination, and the court did not focus on such language. If the plain language does reserve to CMS the power to make revocation determinations, it does not matter that there is statutory authority to delegate that function to contractors. It is a bedrock principle of administrative law that agencies are required to follow their own regulations.[105] It does not matter what a regulation could have said, it matters what it does say. Indeed, in a case where the agency is reversed for not following its own regulation it is understood that the agency had statutory authority to do what it did – if it did not it would have been reversed on *that* ground. It is simply no defense for an agency to say, when challenged on the ground that it failed to follow its regulation, that it could have written the regulation differently. Yet, the ALJ in *Saeed A. Bajwa*[106] permitted CMS to ignore its regulation, saying: "Although 42 C.F.R. § 424.535(a)(3)(i) states that CMS determines whether or not a felony conviction is detrimental, Petitioner cites to no authority and I am aware of none that suggests that the Secretary and CMS cannot delegate that determination to a contractor pursuant to section 1842(a) of the Act."[107] By that reasoning, an ALJ could hold that a supplier's billing privileges were properly revoked for failing to notify the contractor within 20 days of an adverse action on the basis that "although 42 C.F.R. § 424.516(d) states that an adverse action must be reported within 30 days, Petitioner cites to no authority and I am aware of none that suggests that the Secretary and CMS could not have required the reporting be done within 20 days."

When a revocation is challenged on the basis that it was made by a contractor and not CMS, CMS will argue that it actually made the revocation and not the contractor, despite the fact that the revocation is issued on the contractor's letterhead, and all indications are that the determination was written by the contractor. The Medicare Program Integrity Manual, contrary to the regulations, is explicit that contractors may make the revocation determination and issue the revocations,[108] but does state that, for most revocations, the contractor must get prior approval from CMS.[109]

> *Is it unfair to revoke the billing privileges of labs based on the conduct of others and can the underlying basis for the revocation be challenged in the appeal of the revocation?*

Revoking billing privileges of labs for a pattern of incorrect claims is particularly unfair because labs do not determine, and are incapable of determining, medical necessity. Unless a lab knows, or has reason to know, that a physician is ordering services that are not medically necessary (which will typically *not* be the case), there is no good reason for holding the lab accountable for (alleged) mistakes by the ordering physician. How is the Medicare program served by revoking the billing privileges of labs that are not culpable in causing incorrect claims to be filed? Ironically, because section 424.535(a)(8)(ii) applies only to the submitter of the claims, the physician who allegedly made incorrect determinations of medical necessity is not subject to having his or her billing privileges revoked but the lab who submitted the claims is at risk. Moreover, CMS does not necessarily wait until medical necessity denials have been adjudicated through the coverage appeals process, which is separate from the enrollment appeals process[110] (or even until they have adjudicated through a certain level in the coverage appeals process). This means that a physician practice or lab may have its billing privileges revoked for up to three years on the basis of what turns out to be erroneous medical necessity denials.

Because the coverage appeals process is notoriously slow, so much so that its systematic delays are the subject of high-profile litigation in the D.C. Circuit,[111] it is quite possible that even a three-year revocation of billing privileges imposed for alleged incorrect claims will expire before the lab or other provider or supplier will receive an ALJ hearing on its appeal of the medical necessity denials. But can a lab (or other supplier or provider) appeal the revocation and raise the issue of medical necessity in its revocation appeal? The answer would be no, if, consistent with their general approach as described above, the appellate adjudicators will simply look to see if CMS or the contractor determined that there was a pattern or practice

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of submitting incorrect claims and disclaim any authority to look behind that determination and determine whether the claims were in fact incorrect.

The content of the revocation determinations is woefully inadequate

As noted above, the majority of the regulatory bases for revocation do not contain any standards by which to guide the adjudicator. For the few bases that do contain such standards, the revocation determinations are usually silent as to whether the standards were applied or how they were applied. When a revoked supplier challenges the exercise of discretion on appeal, it is told by the ALJ and the DAB that they do not have the authority to overturn the exercise of discretion. There is nothing in the regulations that prevents the review of CMS's or the contractor's exercise of discretion. And if there were, that would be one more example of unfairness. A provider or supplier that has had its billing privileges revoked should be entitled to know that the adjudicator actually considered the regulatory criteria and how it applied those criteria.

A typical example is *Dr. Randy Barnett*, in which the ALJ stated he had "no authority to review CMS's exercise of discretion where discretion is explicitly granted to CMS by regulation."[112] As citation for the proposition that he had no authority to review CMS's exercise of discretion to revoke, however, the ALJ cited an exclusion case,[113] which is not on point for two reasons. First, the OIG's regulations specifically prohibit an ALJ from disturbing the OIG's exercise of discretion to exclude;[114] in contrast, there is no regulatory prohibition on an ALJ or the DAB in reviewing the exercise of CMS's discretion to revoke billing privileges. Second, and much more importantly, the regulatory prohibition on an ALJ in an exclusion case is only on reviewing the OIG's *choice* to exclude – as opposed to imposing some other penalty *once the OIG has established there is basis upon which to exclude*.[115] In contrast, in order to establish the basis for revoking billing privileges due to a felony conviction CMS, or the contractor that (arguably illegally) makes the revocation determination, must determine that the provider's or supplier's continued participation in the Medicare program is contrary to the best interests of the program and its beneficiaries. It is not as though the regulations provide that any felony conviction is per se a basis for some type of adverse enrollment action including revocation and the petitioner on appeal is complaining about the exercise of discretion to revoke versus some lesser penalty. The ALJ in *Barnett* also cited a nursing home termination case,[116] which is off-point for the same reason as the exclusion case, namely that a skilled nursing facility cannot appeal the choice to terminate its provider agreement instead of impose some lesser penalty once CMS has established that grounds for termination exist.[117]

Raising Constitutional and Statutory Challenges to the Revocation Regulations

Seeking a waiver of exhaustion of administrative remedies to procure a temporary restraining order or preliminary injunction (and maybe a decision on the merits)

Although, as described above, there is a multi-step, adversarial administrative appeals process for challenging revocations, constitutional and rulemaking issues cannot be raised during that process.[118]

Therefore, an argument that the revocation regulations violate due process or are procedurally or substantively invalid can be presented only to a federal court. This is not to say, however, that a provider or supplier must necessarily wait until it has exhausted administrative remedies before raising such a challenge. Whereas one usually must wait until one has exhausted administrative remedies, this is not always the case.

The Medicare Statute (title XVIII of the Social Security Act (the "Act")) requires litigants to exhaust administrative remedies before seeking judicial relief on the merits of any claim "arising under" the Medicare Statute.[119] Courts have taken an expansive view as to whether a claim "arises under" the Medicare statute. But Supreme Court decisions on this provision of law have made two points equally clear. The first is that, where a party seeks substantive relief from denial of a claim (*e.g.*, attempting to have a denial of benefits overturned) it must first exhaust administrative remedies. The second point provides an important qualification to this exhaustion requirement: If a party has presented a claim to the Secretary (thereby satisfying the jurisdictional "presentment requirement"),[120] it may proceed to federal court without exhausting administrative remedies if the claim it asserts in court is collateral to a claim for benefits or if exhaustion would be futile.[121]

In *Shalala v. Illinois Council on Long Term Care, Inc.*,[122] the Court rejected the plaintiff's assertion that, under the facts of that case, it was entitled to proceed in federal court without exhausting administrative remedies.[123] But the Court did not purport to – and did not – do away with the principle set forth in *Eldridge* and the other cases that a plaintiff may obtain judicial review of a claim that is collateral to a claim for benefits without having first exhausted administrative remedies. Several decisions have rejected the notion that *Illinois Council* implicitly overruled

Salfi, *Eldridge* and their progeny; rather, these cases make clear that the law remains that a court may excuse a plaintiff's failure to exhaust the Secretary's administrative review process if (1) the claim is collateral to a demand for benefits, or (2) exhaustion would be futile, or (3) irreparable harm would occur if exhaustion were required.[124] A typical post-*Illinois Council* decision is *Niskayuna Operating Co., LLC v. Sebelius*.[125] There the court found that it had jurisdiction to hear the plaintiff nursing facility's motion for injunctive relief because:

> (1) Plaintiff is not directly challenging the decision by the Secretary to terminate Plaintiff's provider agreements, but is merely seeking a stay pending an administrative appeal of the termination decision (i.e., Plaintiff's claims in this Court are entirely collateral to the claim that it is pursuing before the Administrative Law Judge of the United States Department of Health and Human Services, Departmental Appeals Board ("DAB"), and the Secretary), (2) exhaustion would be futile because, by the time a DAB hearing is set and all appeals have been exhausted such that Plaintiff could return to this Court to have it review the propriety of the administrative determination, Plaintiff will almost certainly be out of business, and (3) Plaintiff has shown that it will effectively have no judicial review before irreparable harm ensues.[126]

In *Native Angels Home Health Inc. v. Burwell*,[127] the plaintiff home health agency had its Medicare billing privileges revoked and was provided no due process prior to the revocation. The plaintiff alleged that it was entitled to a pre-deprivation hearing and the court found that the plaintiff satisfied the collateral claim exception to the general rule that exhaustion is required. In so doing, the court followed the earlier decision of the Fourth Circuit in *Ram v. Heckler*,[128] in which a physician alleged a deprivation of procedural due process after his Medicare billing privileges were revoked without benefit of a pre-deprivation hearing. The Fourth Circuit held that the "entirely collateral" exception gave the district court jurisdiction over plaintiff's claim. In *AAA Pharm., Inc. v. United States*,[129] a pharmacy that alleged it was driven out of business by an erroneous revocation of its billing privileges sued the government for money damages. The court denied the government's motion to dismiss, finding that its claim for damages was collateral to a claim for benefits, and therefore the plaintiff was not required to exhaust administrative remedies. Interestingly, the government did not contest the plaintiff's allegation that it had a protected property right.

If one is successful in convincing a court to waive exhaustion, the standard for granting a temporary restraining order ("TRO") or preliminary injunction ("PI") is generally the same throughout the country. One must show irreparable harm, a likelihood of success on the merits and that the public interest weighs in favor of granting the TRO or PI. In the Second Circuit, a colorable constitutional violation is per se irreparable harm.[130] In a jurisdiction where that is not the law, one must show irreparable harm through financial harm. If successful, the plaintiff usually is awarded only procedural relief. For example, the agency enforcement action would be stayed while the plaintiff has the opportunity to present its arguments as to why the enforcement action should not be taken.

In the recent decision of *AHA v. Azar*,[131] however, the district court waived exhaustion and took jurisdiction over the American Hospital Association's ("AHA's") challenge to CMS's 340B discount drug program payment rule, solely on the basis that the challenge to the regulation would have been futile if it were pursued through the administrative appeals process, and addressed the *merits* of the AHA's claim that the rule was ultra vires. That is, the court did not require the AHA to have made a collateral claim for procedural relief, and did not award only procedural relief. If the court's decision stands on appeal, it might pave the way for providers and suppliers to challenge the enrollment regulations as procedurally or substantively invalid without first exhausting administrative remedies and without even the need to present a collateral claim (provided that other courts would be persuaded by the D.C. courts).

Does CMS lack statutory authority to make most revocations?

What might be fairly described as a Hail Mary play, a revoked provider or supplier could challenge the revocation as being contrary to statutory authority. Sections 1102(a) and 1871(a) (1395hh) give the Secretary broad regulatory authority over the administration of the Medicare program.[132] However, the authority to issue monetary sanctions (which is a fair description for at least some retroactive revocations) is generally provided by statute to administrative agencies. Also, the statute provides very little explicit authority for revocations. In comparison to the multitude of grounds for revocation in the regulations, section 1866 of the Act authorizes (but does not require) the Secretary to revoke a provider of services' billing privileges if it has been excluded from participation in federal healthcare programs, or if the Secretary has determined that the provider has been convicted of a felony under federal or state law for an offense that the Secretary determines is detrimental to the best interests of the program or program beneficiaries.[133] Likewise, section 1842 authorizes (but does not require) the Secretary to revoke a supplier's billing privileges if it has been convicted of a felony under federal or state law for an offense which the Secretary determines is

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detrimental to the best interests of the program or program beneficiaries, or if it fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such supplier.[134] Neither section 1866 nor 1842 adds "and such other grounds as the Secretary may determine through regulations" or words to that effect. One wonders why, if the Secretary has inherent authority to revoke billing privileges Congress would have bothered to specify any grounds in the statute for revocation. Moreover, this statutory scheme is in great contrast to the provisions in sections 1128 (the Exclusion Statute) and 1128A (the Civil Monetary Penalty Statute) of the Act, which sets forth a detailed and comprehensive scheme for the Secretary to make mandatory and permissive (a/k/a discretionary) exclusions. Thus, it can be argued that by specifying the grounds in the statute for revocation Congress meant that those would be the exclusive grounds.

Conclusion

The revocation process has serious due process and arbitrary and capricious problems that, thus far, based on the author's interactions with the agency, CMS seems uninterested in remedying. Especially puzzling is that CMS is either unaware of or unconcerned with the bitter taste its actions may be leaving in the mouths of many providers and suppliers, particularly physicians, who are the subject of many or most of the revocation determinations, with the aggressive positions taken by CMS under its regulations.[135] Whatever semblance of a physician/CMS "partnership" that existed at one time is surely being eradicated through the unduly harsh penalties that are being imposed on a regular basis, and without even a fair process.

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Endnotes

1 42 C.F.R. § 424.535(a)(3).

2 The Civil Monetary Penalty ("CMP") Statute provides for sanctions against a person or entity that employs or contracts with an individual or entity that the person or entity knows or should know is excluded from participation in a federal healthcare program, for the provision of items or services for which payment may be made under such a program. *See* section 1128A(a)(6) of the Social Security Act, 42 U.S.C. § 1320a-7a(a)(6). The OIG maintains the LEIE to assist entities to avoid hiring excluded individuals and entities. The LEIE may be accessed at https://oig.hhs.gov/exclusions/exclusions_list.asp.

3 *See* 42 C.F.R. § 424.535(a)(2)(i).

4 *See* 42 C.F.R. § 424.535(e).

5 408 U.S. 464 (1972).

6 408 U.S. at 577.

7 *Id.*

8 The author does not contend that a provider or a supplier has the constitutional right to a full-blown *hearing* pre-revocation – indeed, the are several cases that have held that a provider that has had its provider agreement terminated (which is not the same thing as having its billing privileges revoked) does not have the pre-termination right to a *hearing*. Provider agreement termination cases typically do not deal with a pre-termination *right to respond*, because (in contrast to billing revocations) the regulations give the provider the right to respond prior to the termination of its provider agreement. *See* 42 C.F.R. § 489.53(d).

9 523 F.2d 602, 606 (2d Cir. 1975).

10 797 F.2d 1137 (2d Cir. 1986), cert. denied 479 U.S. 1030 (1987).

11 797 F.2d at 1144-45.

12 878 F.2d 577 (2d Cir. 1989).

13 *Id.* at 582. *See also Green v. Cashman*, 605 F.2d 945 (6th Cir. 1979). In that case, the court also pointed to the discretion of the granting authority to terminate participation, stating, "[w]hatever rights plaintiff-appellee has appear to us to arise exclusively from a contract called a 'Provider' agreement…The agreement between plaintiff-appellee and the State of Ohio is terminable at will on the part of either party." 605 F.2d at 946.

14 *Id.* at 581 (citations omitted).

15 936 F.2d 687, 690 (2d Cir. 1991). *See also Arzt v. Blue Cross & Blue Shield of Greater New York*, 1982 U.S. Dist. LEXIS 15767 (S.D.N.Y. 1982) (health center had a property interest in its expectation of continued participation in the Medicare and Medicaid programs). *But see Gellman v. Sullivan*, 758 F. Supp. 830, 833 (E.D.N.Y. 1991). In *Gellman*, the court cited *Plaza Health* and *Senape* for the proposition that a provider does not have a property interest in its continued participation in the Medicare or Medicaid programs, those cases that found that, where participation can be denied only for cause, there is a property right.

16 156 F.3d 384 (2d Cir. 1998).

17 156 F.3d at 395. The court's decision is a little puzzling because at the time it was issued ALJ appellate decisions did not (and still do not) set policy for CMS. Although the court may have been confused about the effect of ALJ decisions, the larger point is that *Furlong* stands for the proposition that where rules

eliminate or circumscribe the discretion of agency officials, a property right exists.

18 792 F.2d 444 (4th Cir.1986).

19 *Id.* at 447.

20 710 F.2d 1015 (4th Cir. 1983).

21 710 F.2d at 1018.

22 2017 U.S. Dist. LEXIS 112908 (S.D. W.Va. 2017).

23 2017 U.S. Dist. LEXIS 112908, *11.

24 2017 U.S. Dist. LEXIS 112908, *19-21. The test balances (1) the importance of the interest at stake, (2) the risk of an erroneous deprivation of the interest because of the procedures used, and the probable value of additional procedural safeguards, and (3) the government's interest.

25 797 F.2d 119 (3d Cir. 1986).

26 *See id.* at 122 ("we are inclined to doubt whether it can be said as a matter of law… that Ritter had no property interest in his status as a provider").

27 40 F. Supp. 3d 153, 157 (D.D.C. 2014).

28 581 F.2d 1010 (1st Cir. 1978).

29 797 F.2d 858 (10th Cir. 1986).

30 *Id.* at 863, 864. The court's holding also appears to be grounded on its finding that providers and suppliers are not the intended beneficiaries of the Medicare program. *Id.* at 864. *See also N. Mont. Care Ctr. v. Leavitt*, 2006 U.S. Dist. LEXIS 69898 (D. Mont. 2006).

31 67 F.3d 858 (9th Cir. 1995).

32 67 F.3d at 862. *Erickson* was relied upon in *Millman v. Inglish*, 461 Fed. Appx. 627, 628 (9th Cir. 2011).

33 640 F.2d 262 (10th Cir. 1981).

34 797 F.2d at 863.

35 640 F.2d at 264-65.

36 2017 U.S. Dist. LEXIS 99862 (E.D. Tex. 2017).

37 803 F. Supp. 2d. 699 (E.D. Mich. 2011).

38 803 F. Supp. 2d. at 706.

39 Instead, the court said that "the applicable regulatory scheme provided Plaintiff with full opportunities to present relevant evidence and contest the revocation of his Medicare enrollment billing privileges." 803 F. Supp. 2d. at 706.

40 *See* note 32 *supra*.

41 67 F.3d at 862, citing *Vanelli v. Reynolds School Dist. No. 7*, 667 F.2d 773, 777 (9th Cir. 1982); *Roth*, 408 U.S. at 573. A liberty interest can also be implicated if a government action prevents an individual from pursuing the occupation of his or her choice, but courts have held that not being able to participate in Medicare does not rise to the level of being prohibited from pursuing the occupation of a physician or some other healthcare provider or supplier. *See, e.g., Guzman v Shewry*, 544 F.3d 1073, 1085 (9th Cir. 2008) (finding that a physician's temporary suspension from Medicaid did not deny him a liberty interest, and citing *Connecticut v. Gabbert*, 526 U.S. 286, 291-92 (1999) for the proposition that although the Supreme Court has recognized some generalized due process right to choose one's field of private employment, the Court has also emphasized that all cases recognizing such a right have dealt with a complete prohibition on the right to engage in a calling, and not a sort of brief interruption); *Hindley v. HHS*, 2017 U.S. Dist. LEXIS 59983, * 23-24 (N.D. Cal. 2017).

42 67 F.3d at 862, citing *Vanelli*, 667 F.2d at 777-78.

43 314 F.3d 641, 643 (D.C. Cir. 2003).

44 1999 U.S. Dist. LEXIS 18779, *12 (E.D. La. Nov. 30, 1999).

45 239 F. Supp. 3d 266 (D.D.C. 2017).

46 239 F. Supp. 3d at 289.

47 Thus, in 42 C.F.R. § 1001.2001, the OIG provided for notice and an opportunity to respond in writing as well as in person for certain exclusion authorities. *See, e.g.*, 42 C.F.R. § 1001.2001(a) (providing for issuance of a "notice of intent to exclude" which grants 30 days to provide "documentary evidence and written argument in response" prior to imposition of exclusion under certain authorities). The OIG explained that for exclusions under 42 C.F.R. §§ 1001.1301 – 1001.1501, notice and opportunity to respond is not necessary, either because the basis for the exclusion has already been determined by another agency after notice and an opportunity to respond (in the case of §§ 1001.1401, 1001.1501), or the excluded party has been given an opportunity already by the OIG to explain why exclusion should not be imposed (§ 1001.1301). *See* 57 Fed. Reg. at 3319.

48 57 Fed. Reg. at 3319 (bold and underscore added).

49 Section 1902(a)(39) of the Act, 42 U.S.C. § 1396a(a)(39); 42 C.F.R. § 455.416(c). Medicaid is not *required* to revoke until the Medicare appeals are exhausted. 42 C.F.R. § 455.101 (definition of "termination"); *see also* 76 Fed. Reg. at 5943 ("In addition, State Medicaid programs would terminate a provider only after the provider had exhausted all available appeal rights in the Medicare program or in the State that originally terminated the provider or the timeline for such appeal has expired"). However, Medicaid is not *precluded* from revoking prior to the exhaustion of Medicare appeal rights if it has a basis in state law for doing so.

50 *See* 42 C.F.R. §§ 405.372, 405.374, 405.375.

51 42 C.F.R. § 424.535(g).

52 *Id.*

53 Surprisingly, one court referred to the appeals process as an "expedited administrative appeals process." *Native Angels Home Health, Inc. v. Burwell*, 123 F. Supp. 3d 775, 778 (E.D.N.C. 2015).

54 *See* 42 C.F.R. § 405.1063(a). All laws and regulations pertaining to the Medicare and Medicaid programs, including but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

55 *See* below for a discussion of the administrative appeals process. The administrative appeals process consists of a reconsideration, an ALJ hearing, and a Departmental Appeals Board ("DAB") review. *See* 42 C.F.R., Part 498.

56 In at least one case (e.g., *Pacific Labs, LLC*), CMS revised the revocation determination after the supplier requested reconsideration, and then, after issuing the reconsideration, revised the reconsideration after the appeal was pending at the ALJ level, forcing the supplier to start again at the reconsideration level after the ALJ dismissed the hearing request for lack of jurisdiction.

57 *U.S. v. Rogers*, 2001 U.S. Dist. LEXIS 24914, *19 (M.D. Tenn. 2001), *citing Ohio Cast Products v. Occupational Safety & Health*, 246 F.3d 791, 798 (6th Cir. 2001).

58 *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012), citations and some punctuation omitted.

59 *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972). *See also Hoffman Estates v. Flipside, Hoffman Estates, Inc.* 455 U.S. 489, 498 (U.S. 1982); *FCC v. Fox Television Stations, Inc., supra* n. 58 at 2317.

60 There is a strong presumption that all agency action is subject to judicial review, and the exception in the Administrative Procedure Act for agency actions "committed to agency discretion by law," 5 U.S.C. § 701(a), is to be narrowly construed and is given force only when "there is no law to apply." *See Heckler v. Chaney*, 470 U.S. 821, 826-27 (1985), and cases cited therein.

61 42 C.F.R. § 424.535(c).

62 *Id.*

63 42 C.F.R. §§ 424.535(a)(2), (a)(3).

64 *See, e.g., Meadowmere Emergency Physicians, PLLC*, Decision No. CR4971 (Nov. 20, 2017).

65 73 Fed. Reg. 69726, 69940-41 (Nov. 19, 2008).

66 73 Fed. Reg. at 38538.

67 73 Fed. Reg. at 38539 (emphasis added).

68 *Id.*

69 The final rule contains this exchange:

Comment: One commenter stated that they did not agree that a change in practice location should be treated as an urgent matter that would support a retroactive revocation of billing authority.

Response: We disagree with this commenter. Since physicians and NPPs receive payments in part on locality adjustments based on the place of service, we believe that physicians, NPPs, and physician and NPP organizations are responsible for updating their enrollment record within 30 days of a change in practice location. It is also important to note that we already have existing authority to revoke the billing privileges of a Part B supplier, including physicians and NPPs, if CMS or our contractor determines that upon an on-site review or other reliable evidence that the supplier is not operational (see § 424.535(b)(5)). 73 *Fed. Reg.* at 69778.

70 73 Fed. Reg. at 38582.

71 73 Fed. Reg. at 69865, 69866. In a response to a commenter that stated that retroactive revocation creates a situation where Medicare

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denies payment for services physicians have furnished in good faith, CMS merely said that it disagreed with the commenter and that "[w]henever a physician or NPP's State medical license is suspended or revoked, is convicted of felony as described in § 424.535(a)(3), excluded or debarred from participating the Federal exclusion or debarment, or is determined by CMS or our contractor not to be operational, we believe that the payments to these practitioners should immediately cease."

72 There is no regulatory or statutory authority to deny payment to a physician or non-physician practitioner ("NPP") simply because the individual has been convicted of a felony (although a *few* felony convictions are supposed to result in exclusion, and the exclusion would prevent the excluded party from billing Medicare). Whether a physician or NPP can receive Medicare payment despite a license revocation or suspension is more nuanced. The statute and regulations define a "physician" as an individual who is licensed as an M.D. or D.O., and Medicare regulations require that physicians and NPPs must meet all state requirements in order to be paid. However, if a physician is currently licensed in New York where she practices, and has had her license revoked or suspended in Vermont, the latter state's licensing action is no basis to deny her Medicare payment for services furnished to New York Medicare beneficiaries. Likewise, absent a revocation, it does not follow that a provider that has been found to be "non-operational," a term of art that CMS has applied to mean including closed for lunch contrary to posted hours (*see, e.g., Ita Udeobong, d/b/a Midland Care Med. Supply & Equip.*, DAB No. 2324 (2010)) – cannot bill Medicare.

73 42 C.F.R. § 424.535(a)(8)(ii)(A) – (F).

74 *See, e.g.,* Pacific Labs LLC, revocation letter dated November 11, 2015.

75 79 Fed. Reg. at 72514.

76 71 Fed. Reg. 20754 (April 21, 2006).

77 *See, e.g.*, 68 Fed. Reg. at 22072 ("[t]he temporary deactivation of a billing number will not have any effect on a provider or supplier's participation agreement or conditions of participation"); 74 Fed. Reg. at 58119 ("As we previously stated, the deactivation of a provider's Medicare billing privileges is not the same as the revocation of these privileges. A deactivated provider remains enrolled in Medicare, whereas a revoked provider loses its Medicare billing privileges and is no longer enrolled in the program"); 77 Fed. Reg. at 29013 ("While the deactivated provider or supplier would still need to submit a complete enrollment application to reactivate its billing privileges, it would not be subject to other, ancillary consequences that a revocation entails").

78 42 C.F.R. § 424.504.

79 *See, e.g.*, *The American Heritage Dictionary of the English Language*, https://ahdictionary.com/word/search.html?q=restore, ("To bring back to an original or normal condition"); *Merriam-Webster*, https://merriam-webster.com/dictionary/restore?src=search-dict-box ("to bring back to or put back into a former or original state");

80 *See* Medicare Program Integrity Manual ("MPIM"), ch. 15, § 15.27.1 (C) (rev. 462, iss'd May 16, 2013, eff. Mar. 18, 2013 ("If the contractor approves a provider or supplier's reactivation application, the reactivation effective date shall be the provider or supplier's date of deactivation"). *See also Jean-Claude Henry, M.D.*, Decision No. CR4627 ("CMS policy in effect at the time Petitioner filed and signed the application provided that if the contractor approves a provider's or supplier's reactivation application, the reactivation effective date will be the provider's or supplier's date of deactivation. MPIM, ch. 15, § 15.27.1 (C) (rev. 462, iss'd May 16, 2013, eff. Mar. 18, 2013); MPIM, ch. 15, § 15.27.1.2(D) (rev. 474, iss'd Jul. 5, 2013, eff. Oct. 8, 2013)").

81 Section 15.29.4.3 of the MPIM, CMS Pub. 100-08, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c15.pdf.

82 For example, in its update to its policy on payment suspensions, CMS modified Section 8.3.2.2.4 of Chapter 8 of the MPIM to require that a notice of a payment suspension that is issued by a zone program integrity contractor "shall be sent via USPS certified mail or utilizing other commercial mail carriers that allow the tracking of the correspondence to ensure receipt by the provider." Transmittal 670 (Aug. 19, 2016). *See also* 42 C.F.R. § 405.800 (requiring CMS and its contractors to provide notice of a denied enrollment or a billing privilege revocation by certified mail).

83 73 Fed. Reg, 69726 (Nov. 19, 2008).

84 *See* 73 Fed. Reg. at 69766 ("We solicited public comment on two approaches for establishing an effective date for Medicare billing privileges for physician and NPP organizations and for individual practitioners. The first approach would establish the initial enrollment date for physician and NPP organizations and for individual practitioners, including physician and NPPs, as the date of approval by a Medicare contractor. . . .The second approach would establish the initial enrollment date for physician and NPP organizations and individual practitioners, including physicians and NPPs, as the later of: (1) The date of filing of a Medicare enrollment application that was subsequently approved by a fee-for-service (FFS) contractor; or (2) the date an enrolled supplier first started furnishing services at a new practice location.").

85 73 Fed. Reg. 38502 (July 7, 2008).

86 Section 424.555(b) provides:

> No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by a provider or supplier if the billing privileges of the provider or supplier are deactivated, denied, or revoked. The Medicare beneficiary has no financial responsibility for expenses, and the provider or supplier must refund on a timely basis to the Medicare beneficiary any amounts collected from the Medicare beneficiary for these otherwise Medicare covered items or services.

87 For the same reason, CMS's reliance on section 424.5 of the regulations (*see* CMS MSJ at 10) is misplaced.

88 *See e.g., Jean-Claude Henry, M.D.*, Docket No. C-16-276, Decision No. CR4627, at 5-6.

89 *See Urology Group of NJ*, DAB No. 2860 (2018).

90 *See* 73 Fed. Reg. at 72523-24. At one point, the final rule engages in circular logic. The final rule states that a CAP should not be permitted to rescind a revocation for failure to timely notify the contractor of a change in practice location because "we must be promptly notified of all practice location changes so we can ensure that services are only performed at valid locations and, consequently, that payments are made correctly," 79 Fed. Reg at 72523, without grasping that if a provider or supplier has been operating out of a real practice location, the only reason why the location would not be considered "valid" and why payment would be denied is if CMS would not allow a CAP to be applied retroactively. CMS's statement in the CY 2009 PFS Proposed Rule, 73 Fed. Reg. at 38582, "We believe that establishing an expedited reconsideration process will afford providers and suppliers with an administrative remedy similar to a corrective action plan" is simply bizarre. How is a reconsideration process – expedited or not – similar to a CAP? The utility of a CAP is to have a revocation rescinded notwithstanding that there were valid grounds (at least in the eyes of the contractor or CMS) for the revocation. An appeal is only successful if the adjudicator is convinced that the revocation was not valid.

91 *See* 42 C.F.R. § 488.28(a); 488.110(k); 488.408(f).

92 *Leslie Barbour, M.D., LLC*, Docket No. C-16-744.

93 *See* 73 Fed. Reg. 36454 ("while we believe that providers and suppliers can appeal the revocation determination, we do not believe that providers and suppliers can appeal the duration of the re-enrollment bar for Medicare billing privileges"). *See also Vijendra Dave, M.D.*, DAB No. 2672 at 11 (2016).

94 CMS did not attempt to provide a reason as to why one should not be entitled to appeal the length of the reenrollment bar. *See* note immediately above.

95 CMS vests the contractors with determining the length of the reenrollment bar. *See* 73 Fed. Reg. at 46454.

96 42 C.F.R. § 424.535(c)(1).

97 42 C.F.R. § 405.990.

98 42 C.F.R. § 405.990(c)(2).

99 *See* section 1878(f) (1) of the Social Security Act, 42 U.S.C. § 1395oo(f)(1); 42 C.F.R. § 405.1842.

100 Otherwise the appellant could raise a specious regulatory challenge simply to be able to get immediate judicial review on issues that could be decided by the appellate adjudicators.

101 Note that in the CY 2009 Physician Fee Schedule final rule CMS stated that it considered

establishing an expedited *reconsideration* process for those cases which involve a retroactive revocation of billing privileges (i.e., revocation due to exclusion, felony conviction, state license suspension or revocation, or practice location is found to be non-operational), but it believed that an expedited reconsideration process was not warranted (without giving any explanation as to its conclusion). 73 Fed. Reg. at 69865.

[102] *See* § 424.535(a)(3) (revocation for a felony that "CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries"); § 424.535(a)(8)(ii) ("CMS determines that the provider or supplier has a pattern or practice of submitting claims that do not meet Medicare requirements"); § 424.535(a)(14) ("CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part D drugs" that is improper according to the listed criteria).

[103] 75 Fed. Reg. at 72519.

[104] 803 F. Supp. 2d. 699 (E.D. Mich. 2011).

[105] *See, e.g., United States v. Nixon*, 418 U.S. 683 (1974); *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954).

[106] *Saeed A. Bajwa,* CR 4732, *available at* https://www.hhs.gov/sites/default/files/alj-cr4732.pdf.

[107] *Saeed A. Bajwa*, CR 4732, at 12.

[108] *See, e.g.*, section 15.27 of the MPIM ("If circumstances warrant, a fee-for-service contractor shall deactivate or revoke a provider or supplier's Medicare billing privileges under certain circumstances"); 15.24.9, "Revocation Letter Guidance," instructing contractors on what revocation determinations must contain.

[109] Section 15.27.2 of the MPIM.

[110] The coverage appeals process appears at 42 C.F.R, Part 405, Subpart I.

[111] *See AHA v. Price*, 867 F.3d 160 (D.C. Cir. 2017).

[112] CR 1786 (May 8, 2008) at 3.

[113] *Wayne E. Imber, M.D.*, DAB No.1740 (2000).

[114] 42 C.F.R. § 1005.4(c)(5).

[115] *See* 57 Fed. Reg. 3298, ("ALJs may not review the OIG's exercise of discretion to impose a penalty, assessment or exclusion under these authorities. It should also be noted that in a case where the ALJ upholds the OIG's exclusion determination, the ALJ is not authorized under these regulations to modify the date of commencement of the exclusion identified in the OIG's notice of exclusion.").

[116] *Brier Oak Terrace Care Ctr.*, DAB No. 1798 (2001).

[117] 42 C.F.R. § 488.408(g)(2); *see also Rosewood Living Center*, Docket No. A-05-90 (2006).

[118] *See* note 55 *supra.*

[119] Section 205(h) of the Act, 42 U.S.C. § 405(h), as incorporated into Title XVIII of the Act by section 1872 of the Act, 42 U.S.C. § 1395ii.

[120] In *Mathews v. Eldridge*, 424 U.S. 519 (1976), the Court held that the Social Security Act contains both a pure jurisdictional requirement (presentment of a claim) and a waivable requirement (exhaustion of administrative remedies). The presentment requirement recently surfaced in a Medicare case, *AHA v. Azar*, 895 F.3d 822 (D.C. Cir. 2018). *See also Sherman v. Burwell*, 2016 U.S. Dist. LEXIS 103897, n. 2 at *8-9 (D. Conn. 2016) ("Plaintiff has satisfied the requirement for presentment, which only requires that the plaintiff have actually appealed the initial determination – i.e., presented the claim directly to the agency for review under the administrative review process").

[121] *See e.g., Califano v. Sanders*, 430 U.S. 99, 109 (1977) ("[c]onstitutional questions obviously are unsuited to resolution in administrative hearing procedures and, therefore, access to the courts is essential to the decision of such questions"); *Mathews v. Diaz,* 426 U.S. 67, 76 (1976) ("As in *Salfi*, this constitutional question is beyond the Secretary's competence"); *Mathews v. Eldridge*, 424 U.S. 319 (1976); *Weinberger v. Salfi*, 422 U.S. 749, 765, (1975).

[122] 529 U.S. 1 (2000).

[123] The Court held that the requirement of exhaustion of administrative remedies did not apply if there was no administrative appeal process available, reaffirming the principle set forth in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). One may be tempted to argue that the potential length of the administrative appeals process, combined with the inability to raise challenges to the revocation regulations in that process, means that no administrative appeal is *constructively* available. However, thus far this type of argument has not been successful. At least one court has construed *Illinois Council* as meaning literally that no administrative appeal is available. *See Family Rehab., Inc. v. Azar,* 886 F.3d 496, 505 (5th Cir. 2018).

[124] *See, e.g., Sherman v. Burwell*, 2016 U.S. Dist. LEXIS 103897, at *9 (D. Conn. 2016); *Thi of Kan. at Highland Park, LLC v. Sebelius*, 2013 U.S. Dist. LEXIS 112443 (D. Kan. Aug. 9, 2013) (distinguishing between *Illinois Council's* "exception" to the requirement to exhaust administrative remedies and *Eldridge*'s prescription for when waiving exhaustion for "entirely collateral" claims is appropriate); *GOS Operator, LLC v. Sebelius*, 843 F. Supp. 2d 1218, 1230 (S.D. Ala. 2012) (rejecting "the Government's contention that the 'collateral claims' provisions of *Eldridge* did not survive *Illinois Council*"); *Niskayuna Operating Co., LLC v. Sebelius*, 2010 U.S. Dist. LEXIS 118871, 2-3 (N.D.N.Y 2010) ("contrary to Defendants' argument, it does not appear obvious to the Court that the case of [*Illinois Council*] is analogous to the current case").

[125] 2010 U.S. Dist. LEXIS 144292 (N.D.N.Y Oct. 26, 2010).

[126] 2010 U.S. Dist. LEXIS 144292 at *4 (footnotes omitted).

[127] 2015 WL 3657417 (E.D. N.C. 2015).

[128] 792 F.2d 444 (4th Cir. 1986).

[129] 108 Fed. Cl. 321 (Ct. Claims 2012).

[130] *See St. Francis Hosp. v. Sebelius*, 874 F. Supp. 2d 127, 134 (E.D. N.Y. 2012), citing cases.

[131] 348 F. Supp. 3d 62 (D.D.C. 2018).

[132] It is also odd that section 1866 would specify that the Secretary may revoke billing privileges for a provider that has been excluded whereas section 1842 does not do so for suppliers. This omission may further the argument that the statute did not purport to list the exclusive grounds for which a provider or supplier may have its billing privileges revoked.

[133] Section 1866(b)(2)(C) and (D) of the Social Security Act, 42 U.S.C. § 1395cc(b)(2)(C) and (D).

[134] Section 1842(h)(8) and (9) of the Social Security Act, 42 U.S.C. § 1395u(h)(8) and (9).

[135] In addition to the examples already given, note that CMS took the position that section 424.535(a)(1), which authorizes CMS to revoke a provider's or supplier's billing number based on non-compliance with the enrollment requirements applicable to that type of provider or supplier, gave it the authority to revoke any provider or supplier's billing number if the provider or supplier submitted incorrect claims, based on the theory that each enrollment application contains a certification that the provider or supplier will adhere to all Medicare regulations. A series of ALJ decisions followed in which CMS's position was upheld. *See, e.g., City Crown Home Health Agency, Inc.*, No. CR3130 (2014); *Hoyos Home Health Care, Inc.*, No. CR2746 (2013). However, in *Proteam Healthcare, Inc.*, DAB No. 2658 (2015), the DAB reversed CMS's determination that a home health agency's inclusion of the identification number of the incorrect physician on certain claims in itself constituted noncompliance with applicable enrollment requirements and formed a sufficient legal basis to revoke the provider's billing privileges. The DAB found that "CMS's position is inconsistent with the plain language of the regulations and with multiple published statements by CMS about the scope of its revocation authority," DAB No. 2658 at 1, and noted that, under CMS's position, the certification statement in the enrollment applications would convert every Medicare regulation and instruction into a revocable enrollment requirement, DAB No. 2658 at 11. Even after *Proteam* was decided, CMS continued to give an expansive reading of section 424.535(a)(1), *see Pueblo Family Physicians*, No. CR4661 (2016) (reversing revocation under section 424.535(a)(1) that was based on a violation of the reassignment rules). It is unknown whether CMS still subscribes to the view that section 424.535(a)(1) authorizes revocations for noncompliance with any Medicare rule.

Chair's Corner

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REMINDER:

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SUPREME DILEMMA: HANDLING CONFLICTS BETWEEN STATE MEDICAL PRIVACY LAWS AND FEDERAL INVESTIGATIVE SUBPOENAS

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Introduction: An Emerging Conflict

America's healthcare industry attracts federal law enforcement attention and resources like few others. In fiscal year 2018 alone, the U.S. Department of Justice ("DOJ") opened over 1,100 new criminal healthcare fraud investigations.[1] Hundreds of defendants were charged and convicted. Thousands of individuals and entities were barred from participating in Medicare, Medicaid, and other federal programs. An equal number of civil investigations were opened, often overlapping with their criminal counterparts in so-called "parallel proceedings." And physicians, hospitals, pharmacies, research labs, plans, and other healthcare organizations ("HCOs") paid over $2.8 *billion* to the government and private parties in False Claims Act cases in that single fiscal year.[2]

Of all the investigative tools used by law enforcement in conducting these complex, document-heavy investigations, none is more important than the subpoena *duces tecum*. Whether aimed at confirming anomalies in claims data, attempting to corroborate a whistleblower's allegations, or scrutinizing the medical bases for controlled-substance prescriptions, federal agents and prosecutors routinely issue subpoenas to HCOs commanding the production of patient files, billing records, and other sensitive information. Meanwhile, many states have enacted strict medical privacy laws that protect against disclosure of such information without judicial approval, notice to affected patients, or both, attaching serious penalties to violations. As a result, HCOs face a seemingly intractable dilemma upon receipt of a federal subpoena: comply with the demand and run afoul of state privacy law, or refuse and risk sanctions in federal court.

This article addresses the emerging conflict by first reviewing the most common types of federal subpoenas used in healthcare investigations and the authorities on which they rely. It then examines a growing trend of strict state medical privacy laws that constrain the disclosure of patient information. Next, the article summarizes the handful of judicial decisions that have addressed the issue to date, along with examples from other contexts in which the federal subpoena power clashed with state privacy laws. It concludes by identifying other grounds on which to challenge such demands and proposing a framework by which the HCO may devise a response that both minimizes risk to the HCO and protects patient privacy to the fullest extent possible.

Federal Investigative Subpoenas

Federal investigators have a range of options by which to obtain records in investigating cases. Search warrants, which issue only upon a finding of probable cause by a magistrate judge in a criminal investigation, are the most intrusive form of collection and fall outside the scope of this article. Grand jury subpoenas offer an alternative without the hurdle of judicial preauthorization, although they, too, may only be used in criminal matters. A third category encompasses administrative subpoenas, which are frequently employed in criminal, civil, and administrative inquiries in the healthcare industry, and civil investigative demands, an important tool in False Claims Act investigations.

Federal Grand Jury Subpoenas

The most common means by which federal investigators procure documentary evidence in criminal cases is the grand jury subpoena *duces tecum*.[3] The job of the grand jury, whose authority springs from the Fifth Amendment to the United States Constitution, is "to inquire into all information that might possibly bear on its investigation until it has identified an offense or has satisfied itself that none has occurred."[4] In doing so, the grand jury may issue subpoenas without any threshold showing of wrongdoing, subject to certain statutory and constitutional limitations.[5] In practice, it is federal prosecutors who control the grand jury process, deciding whom and what to subpoena without consulting the grand jury beforehand.[6] The recipient of a grand jury subpoena who ignores or refuses the command for productions faces civil and even criminal contempt proceedings in federal court.[7]

The grand jury is meant to work in secret. Grand jurors, prosecutors, and investigators are thus prohibited pursuant to Rule 6(e) of the Federal Rules of Criminal Procedure from disclosing the body's activities to outside parties, including its issuance of subpoenas.[8] These secrecy rules have the effect of barring federal prosecutors from sharing materials obtained by grand jury subpoena with anyone outside the criminal investigative team, meaning that even DOJ lawyers and

investigators involved in parallel civil investigations typically cannot see information produced in response to a grand jury subpoena.[9] Violation of the secrecy rules raises the specter of contempt proceedings, claims of prosecutorial misconduct by any eventual defendant, and even criminal prosecution of the offender.[10]

Recipients of grand jury subpoenas are not bound by the same nondisclosure obligations.[11] Absent a separate court order, the government cannot prevent a grand jury subpoena's recipient from notifying the subject of the investigation – or anyone else – of the government's demand.[12] In the context of healthcare investigations, these interlocking rules have the effect of prohibiting federal prosecutors from disclosing that a grand jury subpoena has been issued or any responsive production with others, including civil investigators, while generally permitting recipients to inform patients and other affected parties of the investigation.

Administrative Subpoenas

Issuing from the executive branch's constitutional duty to enforce the law, administrative subpoenas play an increasingly important role in federal enforcement actions as the lines between criminal, civil, and administrative inquiries blur. These demands, like the agencies that issue them, must be authorized by statute – and a startling range of agencies have received such authority. Indeed, one DOJ study identified 335 distinct administrative-subpoena authorities held by various executive-branch entities.[13] Several are of particular importance to those in the healthcare industry.

First, inspectors general of various federal agencies, including the Department of Health and Human Services ("HHS"), hold broad criminal and civil investigative power to investigate alleged fraud and abuse in federal programs and may issue administrative subpoenas in service of that end.[14] Civil and criminal healthcare fraud investigations routinely involve HHS's requests under this authority.

The DOJ holds a separate administrative-subpoena power in the specific context of criminal healthcare fraud matters, giving its attorneys and investigators, including the Federal Bureau of Investigation, a choice between grand jury and administrative demands for records.[15] Unlike grand jury subpoenas, DOJ administrative subpoenas allow for *ex parte* orders that prohibit the recipient from disclosing the request to any third party for 90 days, which can be renewed indefinitely.[16]

Another authority of particular relevance today is held by the Drug Enforcement Administration ("DEA"), which often takes the lead role in investigations involving the prescription of controlled substances.[17] As the nation's opioid crisis has taken center stage among federal law enforcement priorities, DEA agents regularly issue demands for patient medical and billing records from providers, dispensation histories from pharmacies, and autopsy results from medical examiners to determine whether particular doctors or clinics are prescribing drugs illegally.[18] These requests are often accompanied by letters directing the recipients not to disclose their issuance to any third party for 90 days, which, while not formal court orders, are typically honored by HCOs and have been ruled enforceable by at least one federal court.[19]

Civil investigative demands ("CIDs") provide yet another important means by which the government obtains records in civil healthcare fraud inquiries. In addition to the production of records, CIDs can compel interrogatory responses and testimony under oath.[20] While distinct in name and statutory authority, the courts consider CIDs administrative subpoenas for all practical purposes and will enforce them as such.[21]

Administrative subpoenas share important similarities with their grand jury equivalents. First, unlike a search warrant, no threshold showing of wrongdoing or judicial approval is required to issue them.[22] Indeed, investigators ordinarily need not justify their demands at all. And, as with grand jury subpoenas, the government may seek to enforce compliance in federal court, exposing any party who resists to contempt sanctions.[23]

Administrative subpoenas also offer several unique benefits to investigators. While materials returned in response to grand jury subpoenas typically may not be shared with civil investigators, the converse is not true: evidence gathered by civil administrative subpoena can be used in building a related criminal case.[24] Investigators also appreciate the convenience of administrative subpoenas, which they can issue themselves without going through the prosecutor's office. Finally, unlike the grand jury subpoena, most administrative subpoenas may continue to be used following indictment to gather additional evidence for trial.[25] Given these advantages, administrative subpoenas are often the preferred means of obtaining records in healthcare investigations.

Expanding Medical Privacy Laws

Against the backdrop of aggressive federal enforcement in the healthcare industry stands an assortment of laws designed to protect patient privacy. Some, such as the federal regime, expressly account for the power of investigators to compel the production of medical and billing records by subpoena. Others were drafted without such regard, prohibiting law enforcement from obtaining records absent patient consent or court involvement; in fact, the law of one large state includes a provision that, if followed, would theoretically expose investigators to federal prosecution. Given these competing interests – vigorous enforcement and patient privacy – conflicts are inevitable.

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The Federal Medical Privacy Regime

In 1996, Congress created the best-known medical privacy law, the federal Health Insurance Portability and Accountability Act ("HIPAA"). The law was designed to give patients more control over their protected health information ("PHI") by, among other things, creating nationwide standards restricting the disclosure of patient records by HCOs and other third parties.[26] Recognizing the importance of such information in certain enforcement contexts, however, Congress specifically allowed for disclosure upon receipt of a duly issued subpoena, court order, or warrant.[27] Coupled with the absence of a physician-patient privilege under federal law, these provisions permit investigators to obtain patient PHI without notice to the patient or judicial approval.[28]

State Medical Privacy Laws

Under HIPAA, a state law that imposes "more stringent" protections than the federal government is not preempted.[29] Both before and after HIPAA was passed, many states enacted restrictions on sharing patient PHI, locating them either in specific medical privacy acts of their own, in state-law privileges, or both. These statutes typically call for significant penalties if violated. While a 50-state survey of medical privacy laws is beyond the scope of this article, those of the nation's three largest illustrate this trend.

California's Confidentiality of Medical Information Act, first enacted in 1979, provides for disclosure pursuant to the patient's consent, a judicially authorized search warrant, or a court order.[30] The California Penal Code further specifies that a court order may be obtained only on a showing of "good cause," determined by weighing the need for the information against the resulting injury to the patient, doctor-patient relationship, and the treatment services provided.[31] Therefore, a subpoena issued unilaterally by federal investigators does not suffice to permit disclosure of PHI under California law. Violators face liability for compensatory and punitive damages, attorneys' fees, and criminal prosecution.[32]

The Texas legislature approached the issue differently. The Texas Medical Records Privacy Act, passed in 2011, precludes disclosure of PHI absent patient consent but provides for exceptions "otherwise authorized or required by state or federal law," leaving open the possibility that an investigative subpoena would qualify.[33] The Texas Occupations Code, however, creates a physician-patient privilege covering communications and records concerning "the identity, diagnosis, evaluation, or treatment" of any patient.[34] Abrogation of the privilege generally requires either patient consent or a court order, and no provision allows investigators to obtain such privileged information in the investigative stage.[35] Unauthorized disclosures of privileged information expose the offender to administrative, civil, and criminal penalties.[36]

Similarly, Florida laws enacted in 1999 create a "broad and express privilege of confidentiality" of PHI that generally prohibits disclosure to anyone but the patient, the patient's representative, or other healthcare providers involved in the patient's care, unless the patient provides written authorization.[37] An exception exists that allows providers to disclose patient records upon receipt of a subpoena, but the subpoena must have been approved and issued by a competent court.[38] Moreover, the party seeking the PHI must provide notice to the affected patients so that they have an opportunity to challenge the disclosure request.[39]

Beyond the imposition of additional hurdles to investigators not found in federal law, these provisions of Florida law produce a remarkable result in the context of federal grand jury investigations. As discussed above, Rule 6(e) bars investigating officials from disclosing the grand jury's activities to third parties – a category that would include patients whose records are sought from their providers.[40] To comply with Florida's requirement to notify patients, federal investigators would be forced to violate grand jury secrecy restrictions, theoretically exposing themselves to sanctions and the threat of criminal prosecution. Meanwhile, Florida legislators, potentially oblivious to the conundrum they were creating, mandated fines and other discipline for breaches of their statutory protections.[41]

These three states, which are home to over a quarter of the country's population, have each enacted laws that appear to directly contradict federal investigators' authority to collect evidence by subpoena. Many smaller states have passed similar restrictions of varying rigor.[42] Whether styled as medical privacy statutes or provider-patient privileges, they often contain no exception for investigative subpoenas, and the courts generally have upheld these restrictions against demands from state and local law-enforcement agencies.[43] As a small but growing body of case law makes clear, however, these protections have fared worse in the face of the federal government's broad investigative powers.

Litigating the Conflict

As criminal, civil, and administrative investigations in the healthcare industry continue to rise, so, too, have clashes between federal subpoenas and unyielding state nondisclosure laws. Yet while prosecutors and private counsel report encountering this conflict with growing frequency, published decisions on its resolution

remain rare, issuing mostly from a scattershot of federal district courts across the country. The handful of courts that have addressed the issue have been largely consistent, indicating how such conflicts will be resolved in other jurisdictions while offering guidance to HCOs on responding to federal subpoenas in states with strict medical privacy laws that, on their face, prevent compliance.

Decisions Involving Grand Jury Subpoenas

The few federal courts to consider the question have concluded that the grand jury's authority to investigate potential crimes, including through the issuance of subpoenas, prevails over state laws restricting disclosure. Typically, these decisions rest on the Supremacy Clause of the United States Constitution and the doctrine of conflict preemption, which, in its simplest terms, provides that conflicts between state and federal law are to be resolved in favor of the latter.[44] Occasionally, when addressing physician-patient communication privileges, the courts' analyses focus on the inapplicability of state-law privileges under the Federal Rules of Evidence.[45] Under either analysis, the result is the same, as the following examples illustrate.

In what appears to be the earliest decision directly on point, a federal court in Miami took up this conflict in the context of the predecessor to the Florida medical privacy statute discussed above. In that case, the law had the effect of barring a state agency from disclosing to federal prosecutors the names of patients whom the state agency had investigated.[46] Characterizing the quandary of honoring both the federal grand jury subpoena for the agency's records and the state law as a "physical impossibility," the court summarized a number of other contexts in which federal subpoenas were enforced in violation of state statutes prohibiting disclosure of subpoenaed information, concluding that compliance with the federal subpoena was compelled by the Supremacy Clause.[47] Acknowledging concerns about penalties for violating state law, the court also held that the agency would be immunized from state law sanctions because compliance had been compelled under federal law.[48]

Later, in a rare appellate case on the issue, an Illinois physician appealed a contempt order that had been issued after he had refused to turn over patient medical records in response to a federal grand jury subpoena.[49] The doctor had moved to quash the subpoena on the ground that a state physician-patient privilege prohibited his compliance and exposed him to civil liability and revocation of his medical license were he to violate it. The district court held that a federal grand jury could not be bound by state law privileges under the Supremacy Clause and ruled that the doctor could not be penalized for complying with the federal subpoena.[50] The Seventh Circuit upheld the lower court's order, although it shifted its focus from preemption to the principle that state law privileges do not apply under the Federal Rules of Evidence.[51] In any case, the doctor was forced to turn over the records to federal investigators.

More recently, a district court in Maine reached the same result when a local hospital refused to produce documents containing PHI in response to a federal grand jury subpoena, again citing a state law that prohibited disclosure.[52] The court reasoned that HIPAA's anti-preemption provision, which allows states to craft more stringent privacy protections than the federal regime, was not intended to give state law an effect that it otherwise would not have had, such as applying state restrictions to federal activity.[53] The court concluded that the Maine statute did not apply to federal grand jury investigations and denied the hospital's motion to quash the federal grand jury subpoena.[54] District courts elsewhere have held similarly, again basing their decisions on the supremacy of federal law and the inapplicability of state privileges to federal proceedings.[55]

These rulings accord with those of other courts addressing clashes between federal investigations and state laws protecting other types of sensitive information. For example, a U.S. district judge in Austin ordered an accountant to comply with a federal grand jury subpoena despite a provision in the Texas Occupations Code prohibiting accountants from disclosing client records without a court order.[56] The court declared the state statute preempted under the Supremacy Clause while shielding the accountant from civil liability under state law or accounting board disciplinary action for his compliance.[57] This decision echoed others in contexts ranging from state bar investigations to bank secrecy rules.[58] In short, while there remains a lack of controlling precedent in most circuits, the lower courts' consistency on the issue suggests that future challenges to federal grand jury subpoenas based on state nondisclosure provisions will fail.

Decisions Involving Administrative Subpoenas

Perhaps surprisingly, courts have addressed the conflict created by strict state medical privacy laws more often in the context of administrative subpoenas, particularly in recent years. It is unclear whether this disparity stems from federal investigators' preference for administrative subpoenas in healthcare investigations, HCOs' greater willingness to challenge such demands, or something else. Whatever the reason, the outcome is the same: administrative subpoenas prevail over state privacy protections.

A recent Fifth Circuit opinion illustrates the point. In that case, a Texas doctor refused to produce patient medical records in response to a DEA administrative subpoena issued

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pursuant to its authority under the Controlled Substances Act ("CSA").[59] The doctor based his refusal in part on Texas's physician-patient privilege, discussed above. The Fifth Circuit upheld the lower court's enforcement order, finding that the state provision created a direct conflict with the DEA's subpoena power and was therefore preempted by the CSA.[60]

The Ninth Circuit reached the same result in a 2017 case involving a DEA subpoena to Oregon's Prescription Drug Monitoring Program ("PDMP").[61] Oregon law prohibited disclosure of PDMP data to law enforcement absent a court order based on probable cause.[62] Deeming Oregon's requirement for judicial authorization of subpoenas a "significant obstacle" to the full implementation of the CSA, the appellate court declared the state law preempted.[63] At least two other district courts have relied on the supremacy of federal law to reject challenges to DEA subpoenas for other states' PDMP data.[64]

The DEA has not been alone in its success. Nearly three decades ago, a district court in Iowa ordered a hospital to comply with an HHS subpoena seeking a physician's medical records in a civil investigation, declaring a state law prohibiting such disclosures preempted by HHS's subpoena power.[65] Years later, a federal judge in New York ordered an HCO to disclose mental health records in response to a Social Security Administration ("SSA") administrative subpoena despite a state law prohibiting disclosure, further directing the HCO to cover costs incurred by the SSA in litigating the motion to compel.[66] More recently, an Ohio physician-patient privilege was determined not to protect against disclosure pursuant to CIDs issued by a U.S. Attorney in Alabama, the district court finding the state law inapplicable to a federal investigation.[67] A number of other courts have deemed administrative subpoenas for sensitive records enforceable in the face of state privileges and nondisclosure provisions in the healthcare context and other industries.[68]

Other Challenges to Federal Subpoenas

The cases above make clear that an HCO's refusal to comply with a federal subpoena on the basis of state privacy law is unlikely to succeed and may expose the organization to sanctions and court costs. Yet the HCO is not without recourse when faced with an objectionable demand from federal authorities. Where a federal subpoena requests records covered by a privilege recognized in federal law, advances an improper purpose, or is overbroad in its scope, it may be modified or quashed on motion to the district court.

Recognized Federal Privileges

Although the Federal Rules of Evidence generally do not apply to grand jury proceedings, recognized federal common-law privileges do, thus protecting certain communications from compelled disclosure.[69] In the context of healthcare investigations, the most pertinent shields are the attorney-client, work-product, and psychotherapist-patient privileges.[70] Further, while an individual who receives a subpoena *duces tecum* typically cannot resist production on the ground that the documents may inculpate a third party, that person may assert a Fifth Amendment privilege in limited circumstances, such as where the recipient is the target of the investigation.[71]

Regardless of the privilege claimed, the party invoking its protection bears the burden of showing that the requested materials fit within it.[72] Once that burden has been met, the court will modify or quash the subpoena unless an exception applies.[73] Failure to timely assert the privilege may result in waiver, requiring a careful privilege analysis before any documents are produced.

Improper Purposes

Courts will also exercise their supervisory authority to block subpoenas issued for improper purposes. As noted earlier, grand jury subpoenas cannot be used to gather evidence for trial after an indictment has been returned, while CIDs may not be issued after the government intervenes in a *qui tam* or files a direct complaint in a civil false claims action.[74] Consideration of the procedural posture of the case is thus imperative. The issuance of grand jury subpoenas to procure evidence for a purely civil or administrative investigation is also *per se* improper.[75] Other forms of prosecutorial misconduct, such as harassment, intimidation, and selective or vindictive prosecution, constitute improper purposes as well.[76] Again, however, the recipient bears the burden of making an initial showing of an invidious government motive to see the subpoena quashed, and successful challenges on such grounds are rare.[77]

Fourth Amendment "Unreasonableness"

Finally, overbroad or irrelevant demands may be properly resisted. The Fourth Amendment creates a constitutional right to be free from unreasonable searches and seizures.[78] As previously discussed, unlike search warrants, no showing of probable cause or any lesser standard of suspicion is required to issue a grand jury or administrative subpoena.[79] Nevertheless, a subpoena *duces tecum* must be reasonable in its scope.[80] While a duly issued grand jury subpoena is presumed reasonable, it must seek "information relevant to the grand jury's investigation,"[81] although relevancy in the grand jury context is

defined far more broadly than at trial.[82] A demand for records "too sweeping in its terms to be regarded as reasonable" is subject to challenge, a standard that applies equally to administrative subpoenas.[83]

Where a request is obviously overbroad or the records sought are patently irrelevant to the investigation, the recipient may move to quash, but it is usually advisable to confer with the government first in an effort to narrow the scope of the demand.[84] Claims of unreasonableness require a "strong showing" by the subpoena's challenger – a burden that challengers usually struggle to meet, as secrecy rules will often obscure the breadth of the investigation.[85] Despite these hurdles, courts have occasionally found federal demands unreasonably broad and exercised their authority to modify or quash them.[86] An important consideration in certain cases has been investigators' ability to obtain the information sought by other means.[87] At least one court has found that the sheer volume and duplicative nature of the subpoenaed materials warranted quashing.[88] The lesson from these decisions is that, unlike challenges based on state privacy protections, an HCO in receipt of an unnecessarily expansive subpoena for records should not be discouraged from raising its concerns with the court, particularly if the government has proven unwilling to curtail its request.

Conclusion: Handling Federal Subpoenas Amidst Tightening State Privacy Restrictions

The conflict between state medical privacy laws and federal subpoenas in the healthcare industry is an emergent one. While case law directly on point is limited, the decisions that do exist consistently affirm that federal subpoenas, whether issued by a grand jury or an administrative agency, prevail over privacy provisions created under state laws under the doctrine of conflict preemption. Hence, the HCO is unlikely to succeed in refusing to comply with federal subpoenas on the ground that state law does not permit disclosure, and refusal may needlessly expose the organization to costs and penalties. Nevertheless, before producing such sensitive information in contravention of state law, counsel would be wise to consider how best to minimize risks to the organization.

First, counsel should determine whether a recognized federal privilege, such as attorney-client or work-product protection, applies to the requested records. Second, confirm that the documents are not being sought by the government for some improper purpose, such as post-indictment trial preparation. Third, evaluate the scope of the request, considering whether it may be challenged as overbroad or otherwise unreasonable and what, if any, more narrowly defined production would be acceptable. Factors important to this determination may include the volume of documents sought, whether they have been produced previously by the HCO or another party, and their availability to investigators from a different source that would not require a violation of state law.

Where any of these concerns exist, counsel should confer with the government with the aim of winnowing the request. If informal efforts to narrow the subpoena fail, the HCO may move to modify or quash the subpoena. Regardless, counsel should consider seeking a declaration from a federal court that the HCO will be immunized against state law penalties for disclosing protected records pursuant to the federal subpoena. Additionally, it may also be advisable to seek a protective order barring further disclosure of the production, as it would demonstrate the HCO's efforts to protect patient information to the fullest extent possible despite its inability to refuse compliance. Lastly, the HCO should determine whether it is prohibited by governmental directive or court order from notifying affected patients or other parties of the production and, if not, decide whether to provide such notice as a matter of state law or organizational policy.

Although disclosing records in violation of state medical privacy laws is doubtless unappealing to individuals and organizations that take seriously their obligations under state law to safeguard such sensitive information, the supremacy of the federal government's subpoena power will sometimes demand it. Given the aggressive enforcement environment in which HCOs currently operate, counsel is increasingly likely to encounter this conflict, presenting an unpalatable choice between potential state law penalties on the one hand, and the prospect of enforcement proceedings in federal court on the other. Following the approach outlined above may offer the HCO its best chance at avoiding both fates, minimizing the threat of needless litigation costs and possible sanctions while maximizing the protection of patient health information. In short, while the risk created by this dilemma cannot be entirely resolved, it can be intelligently managed, thereby best serving the interests of both the HCO and the many patients in its care.

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Endnotes

1 *See* Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report* (2018), https://oig.hhs.gov/publications/docs/hcfac/FY2018-hcfac.pdf.

2 Department of Justice, *Press Release: Justice Department Recovers Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018* (Dec. 21, 2018), https://justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018.

3 Fed. R. Crim. P. 17(c).

4 *United States v. R. Enterprises, Inc.*, 498 U.S. 292, 297 (1991); *see also* U.S. Const., amend. V, cl. 1.

5 498 U.S. at 297 ("[T]he Government cannot be required to justify the issuance of a grand jury subpoena by presenting evidence sufficient to establish probable cause because the very purpose of requesting the information is to ascertain whether probable cause exists.").

6 *See In re Grand Jury Proceedings*, 486 F.2d 85, 90 (3d Cir. 1973) (describing grand jury subpoenas as "almost universally instrumentalities of the United States Attorney's Office"); *Lopez v. Department of Justice*, 393 F.3d 1345, 1349 (D.C. Cir. 2005) (calling term "grand jury subpoena" a "misnomer," given prosecutor's control over issuance).

7 *See, e.g.*, 28 U.S.C. § 1826 (authorizing imprisonment of recalcitrant witnesses in proceedings before federal courts and grand juries); 18 U.S.C. §§ 401 and 402 (providing for punitive measures and criminal prosecution of recalcitrant persons); Judiciary Act of 1789, 1 Stat. 73 (granting federal courts power "to punish by fine or imprisonment . . . all contempts of authority in any cause or hearing" before them).

8 Fed. R. Crim. P. 6(e)(6); *see also, e.g., Index Fund v. Hagopian*, 512 F. Supp. 1122, 1128 (S.D.N.Y. 1981) (documents, not simply testimony, are subject to grand jury secrecy provisions).

9 *United States v. Sells Engineering, Inc.*, 463 U.S. 418, 428-31 (1983).

10 *See* Fed. R. Crim. P. 6(e)(7) (knowing violations of secrecy obligations punishable as contempt of court); *United States v. Forman*, 71 F.3d 1214, 1220 (6th Cir. 1995) (violators of secrecy rules may be prosecuted for criminal contempt and obstruction of justice).

11 *See* Fed. R. Crim. P. 6(e)(2) (prohibiting obligation of secrecy on a person except grand jurors, prosecutors and investigators involved in the investigation, and individuals facilitating the taking and recording of testimony, such as court reporters and interpreters).

12 *See In re Grand Jury Proceedings*, 814 F.2d 61, 70 (1st Cir. 1987) (finding government letter imposing 90-day nondisclosure obligation on subpoena recipients violated Rule 6(e)(2)); *United States v. Radetsky*, 535 F.2d 556, 569 (10th Cir. 1976) (admonition to witness not to disclose testimony violated Rule 6(e)(2)); *cf.* 12 U.S.C. § 3409 (authorizing court order delaying financial institution from notifying customer of grand jury subpoena); 18 U.S.C. § 2705(b) (authorizing court-issued nondisclosure order under Stored Communications Act).

13 Office of Legal Policy, United States Department of Justice, *Report to Congress on the Use of Administrative Subpoena Authorities by Executive Branch Agencies and Entities*, 7 (2002), https://www.justice.gov/archive/olp/rpt_to_congress.htm.

14 *See* 5 U.S.C. § App. 3 § 6(a)(4) (source of subpoena power); *see also* S.Rep. 1071, 95th Cong., 2d Sess. 34 (1978), reprinted in 1978 U.S.C.C.A.N. 2676, 2709 (describing purpose of Inspector General Act).

15 18 U.S.C. § 3486(a)(1)(A).

16 18 U.S.C. § 3486(a)(6). Such orders require a justification of potential danger, risk of flight, spoliation, or witness intimidation.

17 *See, e.g.*, Drug Enforcement Administration, *Press Release: Doctor, Office Administrator and Nurse Practitioner Selling Prescriptions for Fentanyl and Oxycodone: Dr. Ernesto Lopez Charged $2 Million in Fees to "Patients,"* (Nov. 2, 2017), https://dea.gov/divisions/nyc/2017/nyc110217.shtml; Drug Enforcement Administration, *Press Release: Pill Mill Doctor Pleads Guilty to Drug Distribution Conspiracy, Money Laundering* (Jan. 30, 2017), https://www.dea.gov/divisions/no/2017/no013017.shtml.

18 21 U.S.C. § 876(a) (authorizing Attorney General to issue administrative subpoenas in controlled substance investigations); 28 C.F.R. § 0.100 (delegating authority to DEA).

19 *See United States v. Mountain States Tel. & Tel. Co.*, 516 F. Supp. 225, 233 (D. Wyo. 1981).

20 31 U.S.C. § 3733.

21 *See United States v. Markwood*, 48 F.3d 969, 976 (6th Cir. 1995) (FCA CID); *United States v. Witmer*, 835 F. Supp. 208, 220 (M.D. Pa. 1993), *aff'd*, 30 F.3d 1489 (3d Cir. 1994) (same); *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1087 (D.C.Cir.1992) (FTC CID); *see also* 31 U.S.C. § 3733(j)(6) (Federal Rules of Civil Procedure do not apply if their application is inconsistent with Section 3733).

22 *See, e.g., Doe v. United States*, 253 F.3d 256, 263 (6th Cir. 2001).

23 *See* 5 U.S.C. § App. 3 § 6(a)(4) (enforcement of Inspectors General subpoenas); 18 U.S.C. § 3486(c); 21 U.S.C. § 876(c) (enforcement of DEA subpoenas); 31 U.S.C. § 3733(j)(1) (enforcement of CIDs).

24 *See, e.g., United States v. Aero Mayflower Transit Co.*, 831 F.2d 1142, 1146 (D.C. Cir. 1987) (permitting cooperation between Inspector General and criminal prosecutors); *see also* 31 U.S.C. § 3733(i) (permitting custodian of CID production to share with DOJ attorneys for grand jury purposes).

25 *See, e.g., United States v. Phibbs*, 999 F.2d 1053, 1077 (6th Cir. 1993) (administrative subpoenas "may be used to discover evidence related to the charges in the original indictment"); *cf.* USAM 9-11.120 (grand jury subpoena "cannot be used solely to obtain additional evidence against a defendant who has already been indicted . . . [or] for pre-trial discovery or trial preparation") (citations omitted). Note, however, that in False Claims Act cases, CIDs may be used only before the government files a complaint of its own, be it directly or in intervention in a *qui tam* suit. *See* 31 U.S.C. § 3733(a)(1).

26 HIPAA Privacy Rule, 45 C.F.R. Part 160 and Subparts A and E of Part 164. PHI is defined as "individually identifiable health information" relating to a past, present, or future physical or mental health condition, the provision of healthcare, or payment for healthcare that identifies or could be used to identify the subject of the information. 45 C.F.R. § 164.501.

27 45 C.F.R. § 164.512(f)(1)(ii).

28 *Whalen v. Roe*, 429 U.S. 589, 608 n. 28 (1977) ("The physician-patient evidentiary privilege is unknown to the common law."); *but see* 42 U.S.C. § 290dd-2 (imposing additional federal privacy protections on and requiring court order for records related to substance abuse programs with federal nexus).

29 45 C.F.R. § 160.202(b); 42 U.S.C. § 1320d-7 (a)(2)(B).

30 Cal. Civ. Code § 56.10(b); *cf.* Cal. Evid. Code §§ 994 and 998 (creating physician-patient privilege under state law but rendering it inapplicable to criminal proceedings).

31 Cal. Penal Code § 1543(a).

[32] Cal. Civ. Code §§ 56.35 and 56.36.

[33] Tex. Health and Safety Code §§ 181.001 *et seq* (enacted in 2011).

[34] Tex. Occ. Code § 159.002(a), (b) and (e).

[35] The statute contains various exceptions where the patient is a party to ongoing litigation or, in the criminal context, after an *in camera* review by the court. *See id.* § 159.003.

[36] *See* Tex. Occ. Code §§ 165.151 *et seq.*

[37] *Acosta v. Richter,* 671 So. 2d 149, 154 (Fla. 1996) (discussing purpose of Florida medical privacy laws); *see also* Fla. Stat. §§ 395.3025(4)(d) and 456.057(7)(a)(3) (nondisclosure provisions governing hospitals and physicians, respectively).

[38] Fla. Stat. §§ 395.3025(4)(d) and 456.057(7)(a)(3).

[39] *Id.*; *see also State v. Johnson*, 814 So. 2d 390, 393 (Fla. 2002) (noting purpose of notification requirement).

[40] *See* n. 9 *supra.*

[41] *See* Fla. Stat. § 456.057(15) and (16).

[42] *See, e.g.,* Ohio R.C. § 2317.02(B)(1); Me. Rev. Stat. tit. 22, § 1711-C; Or. Rev. Stat. Ann. § 192.558.

[43] *See, e.g., Turk v. Oiler*, 732 F. Supp. 2d 758, 777 (N.D. Ohio 2010) (noting Ohio state law contained no exception to privilege for state grand jury subpoena).

[44] U.S. Const., art. VI, § 2. The doctrine of conflict preemption demands that federal law prevails where "compliance with both federal and state regulations is a physical impossibility . . . and those instances where the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (internal quotations omitted) (citations omitted).

[45] *See, e.g., In re Zuniga*, 714 F.2d 632, 636 (6th Cir. 1983) ("[I]nasmuch as the subpoenas in issue are the product of a federal grand jury investigation into alleged violations of federal criminal law, questions of privilege are governed by federal law.") (citation omitted).

[46] *In re Grand Jury Matter*, 762 F. Supp. 333, 334 (S.D. Fla. 1991). This decision did not address the current provision requiring notice to the patient by the issuing party, which would violate the grand jury secrecy requirements of Rule 6(e).

[47] *Id.* at 334-35 (citations omitted).

[48] *Id.* at 336 (physician could not be said to willfully violate state statute by complying with federal law).

[49] *Matter of Grand Jury Proceedings Krynicki*, 2 F.3d 1153 (7th Cir. 1993).

[50] *Id.* at *1.

[51] *Id.* at *4. Privileges in federal court are governed by federal statute, the Constitution, and federal common law, not state law. Fed. R. Evid. 501; *see also United States v. Gillock,* 445 U.S. 360, 368 (1980); *United States v. Burzynski Cancer Research Institute*, 819 F.2d 1301, 1311 (5th Cir.1988) ("In the context of federal criminal proceedings, no physician-patient privilege exists.").

[52] *In re Grand Jury Proceedings*, 450 F. Supp. 2d 115 (D. Me. 2006); *see also* Me. Rev. Stat. tit. 22, § 1711-C.

[53] 450 F. Supp. at 117.

[54] *Id.* at 119.

[55] *See, e.g., In re Grand Jury Subpoena*, 460 F. Supp. 150, 151 (W.D. Mo. 1978) (state physician-patient privilege does not apply to federal grand jury proceeding); *United States v. Sutherland*, 143 F. Supp. 2d 609, 611 (W.D. Va. 2001) (state privacy right does not obtain in federal criminal proceedings); *In re Grand Jury Subpoena John Doe No. A01-209*, 197 F. Supp. 2d 512, 515 (E.D. Va. 2002) (no state physician-patient privilege in context of federal grand jury investigation); *but see In re Grand Jury Subpoena for THCF Med. Clinic Records*, 504 F. Supp. 2d 1085, 1091 (E.D. Wash. 2007) (holding that while "[i]t is clear that the State's sovereignty can be trumped by a federal subpoena" under Supremacy Clause, grand jury subpoena for medical records was unreasonable given the records' marginal probativeness, contrary state privacy laws, and the availability of the information sought from other sources).

[56] *In re Grand Jury Proceedings*, 607 F. Supp. 2d 803 (W.D. Tex. 2009) (examining Tex. Occ. Code. § 901.457 and 22 Tex. Admin. Code § 901.457).

[57] *Id.* at 807.

[58] *See, e.g., United States v. Silverman*, 745 F.2d 1386, 1398 (11th Cir. 1984) (finding Florida law protecting confidentiality of bar complaints inapplicable in federal prosecution of attorney); *United States v. Supreme Court of New Mexico*, 839 F.3d 888, 928 (10th Cir. 2016), *cert. denied,* 138 S. Ct. 130 (2017), and *cert. denied,* 138 S. Ct. 78 (2017) (declaring state law restrictions on subpoenaing attorneys preempted by federal grand jury subpoena power); *In re Grand Jury Subpoena*, 688 F.Supp. 319, 320 (W.D.Tenn.1988) (Tennessee statute barring disclosure of bank records from disclosure preempted by federal grand jury subpoena); *but see In re Hampers*, 651 F.2d 19 (1st Cir. 1981) (finding Massachusetts Commissioner for Revenue enjoyed qualified privilege against grand jury subpoena for tax records).

[59] *United States v. Zadeh*, 820 F.3d 746 (5th Cir. 2016); *see also* 21 U.S.C. § 876.

[60] *Id.* at 752.

[61] *Oregon Prescription Drug Monitoring Program v. U.S. Drug Enf't Admin.*, 860 F.3d 1228 (9th Cir. 2017).

[62] Or. Rev. Stat. § 431A.865(2)(a)(G).

[63] 860 F.3d at 1236.

[64] *See United States Dep't of Justice v. Utah Dep't of Commerce*, No. 2:16-CV-611-DN-DBP, 2017 WL 3189868, at *9 (D. Utah July 27, 2017) (finding preemption provision of CSA defeats state law requiring search warrant to obtain PDMP data); *U.S. Dep't of Justice v. Colorado Bd. of Pharmacy*, No. 10-CV-01116-WYD-MEH, 2010 WL 3547896, at *1 (D. Colo. Sept. 3, 2010) (finding Colorado law restricting release of PDMP data to patients, not prescribers, preempted by CSA).

[65] *St. Luke's Reg'l Med. Ctr., Inc. v. United States*, 717 F. Supp. 665, 666 (N.D. Iowa 1989). The court in this case also issued a protective order to prevent further distribution of the medical records at issue.

[66] *Massanari v. NW. Community Mental Health Ctr.*, No. 01-MC-50E, 2001 WL 1518137, at *1 (W.D.N.Y. Nov. 7, 2001) (declaring state law prohibiting disclosure "a nullity" in face of SSA subpoena under Supremacy Clause).

[67] *Cleveland Clinic Found. v. United States*, No. 1:11MC14, 2011 WL 862027, at *2 (N.D. Ohio Mar. 9, 2011).

[68] *See, e.g., Gilbreath v. Guadalupe Valley Hosp. Found., Inc.*, No. SA-92-CA-0031, 1992 WL 551409, at *4 (W.D. Tex. Oct. 9, 1992), *aff'd sub nom. Gilbreath v. Guadalupe Hosp. Found. Inc.*, 5 F.3d 785 (5th Cir. 1993) (holding Texas physician-patient privilege inapplicable to subpoena issued by U.S. Merit Systems Protection Board); *United States ex rel. Agency for Int'l Development v. First National Bank of Maryland,* 866 F.Supp. 884, 886-87 (D. Md. 1994) (federal subpoena need not comply with notice requirements of Maryland Right To Financial Privacy Act); *In re Subpoena To Testify Before Grand Jury*, 787 F. Supp. 722, 724 (E.D. Mich. 1992) (grand jury subpoena for records enforceable over state accountant-client privilege); *cf. Northwestern Memorial Hosp. v. Ashcroft*, 362 F.3d 923, 932 (7th Cir. 2004) ("[C]omity 'impels federal courts to recognize state privileges where this can be accomplished at no substantial cost to federal substantive and procedural policy.'"). While the courts will enforce a federal subpoena in the face of a conflicting state privacy law, the latter remains effective as to state and local authorities.

[69] *See* Fed. R. Evid. 501 and 1101(d)(2).

[70] *See Fisher v. United States*, 425 U.S. 391, 403 (1976) ("Confidential disclosures by a client to an attorney made in order to obtain legal assistance are privileged."); *Upjohn Co. v. United States*, 449 U.S. 383, 397 (1981) (applying work-product doctrine to IRS subpoenas); *Jaffee v. Redmond*, 518 U.S. 1, 13 (1996) (affirming communications between psychotherapist and patient are protected from compelled disclosure under Rule 501).

[71] 425 U.S. at 410-11; *see also United States v. Hubbell*, 530 U.S. 27, 36-37 (2000) ("[T]he act of producing documents in response to a subpoena may have a compelled testimonial aspect."). A corporate or other collective entity, however, may not assert a Fifth Amendment privilege, nor may an individual who possesses corporate records only in a representative capacity. *See Bellis v. United States*, 417 U.S. 85, 88 (1974).

[72] *United States v. Kovel*, 296 F.2d 918, 923 (2d Cir. 1961).

[73] *See In re Grand Jury Proceedings #5 Empanelled Jan. 28, 2004*, 401 F.3d 247, 251 (4th Cir. 2005) (discussing crime fraud exception to attorney-client privilege); *In re Horowitz*, 482 F.2d 72, 82 (2d Cir. 1973) (discussing waiver of attorney-client privilege).

[74] *See* n. 24 *supra.* A *qui tam* action, the abbreviation of a Latin phrase meaning "who brings the action for the king as well as himself," permits a private whistleblower (called a "relator") to bring suit under the False Claims Act against one or more defendants alleged to have defrauded the federal government. *See* 31 U.S.C. §§ 3729-3733.

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75 463 U.S. at 432.

76 410 U.S. at 11.

77 498 U.S. at 301.

78 *See Mapp v. Ohio*, 367 U.S. 643 (1961); U.S. Const., amend. IV.

79 *See* n. 5 *supra*.

80 *In re Subpoena Duces Tecum*, 228 F.3d 341, 347 (4th Cir. 2000) (citing *Hale v. Henkel*, 201 U.S. 43, 76, 26 S.Ct. 370, 50 L.Ed. 652 (1906)).

81 498 U.S. at 301-02.

82 *Id.* at 301 ("[T]he motion to quash must be denied unless the district court determines that there is no reasonable possibility that the category of materials the Government seeks will produce information relevant to the general subject of the grand jury's investigation.

83 *United States v. Dionisio*, 410 U.S. 1, 11 (1973) (internal quotations omitted) (citations omitted); *see also* Fed. R. Crim. P. 17(c)(2) (requiring that subpoena not be "unreasonable or oppressive"); 228 F.3d at 347 (citing *See v. City of Seattle*, 387 U.S. 541, 544 (1967)); *see also United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 817 (8th Cir. 2012) ("A subpoena is properly enforced if (1) issued pursuant to lawful authority, (2) for a lawful purpose, (3) requesting information relevant to the lawful purpose, and (4) the information sought is not unreasonable.").

84 Fed. R. Crim. P. 17; *see also* 228 F. 3d at 350.

85 498 U.S. at 302.

86 *See, e.g., In re Grand Jury No. 09-1*, No. 6:10MC38ORL31DAB, 2010 WL 2330273, at *8 (M.D. Fla. June 10, 2010) (quashing grand jury subpoena as overbroad); *United States v. Sutherland*, 143 F. Supp. 2d 609, 613 (W.D. Va. 2001) (modifying grand jury subpoena to require patient notice despite Rule 6(e)(2) secrecy provisions).

87 *See THCF Medical Clinic Records*, 504 F.Supp 2d at 1090 ("The Government has not shown why it needs to obtain all of the addresses and phone numbers from the State of Oregon and the THCF Medical Clinic rather than from some other source."); 651 F.2d at 23 (finding qualified privilege under state law against disclosure of state tax records to federal grand jury given government's alternate means to obtain same records under provision of tax code).

88 *See In re Grand Jury Investigation*, 746 F. Supp. 866, 867 (E.D. Wis. 1990).

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LESSONS LEARNED FROM A NEW MEDICAL-LEGAL PARTNERSHIP: PATIENT SCREENING, INFORMATION AND COMMUNICATION

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Introduction

The United States spends significantly more on healthcare than any other nation.[1] Yet the health of the nation's population is inferior to that of many other nations that spend significantly less on healthcare.[2] Access to healthcare can be essential to an individual's maintaining or returning to good health. But the social determinants of health are at least as important. Moreover, social determinants play a significant role in facilitating or limiting access to healthcare.[3]

The social determinants of health have been identified as "the conditions in which people are born, grow, live, work and age."[4] Further, the social determinants of health, including the slope of a society's socio-economic hierarchy and a person's place on that hierarchy, have a greater impact on health than individual choices (which are, themselves, influenced by a person's socio-economic status).[5] Strikingly, the United States spends more on healthcare per capita than any other nation, and it spends significantly less on social services.[6] That choice could undermine the nation's health.

The health of people who face health-harming legal needs – such as adequate and nutritious food, safe housing, and a safe environment – is compromised by those unmet needs. In addition, the stress of having adverse social determinants of health and health-harming legal needs can further impact health negatively. For instance, stress has been shown to be an independent risk factor for poor health. Fortunately, it can be mitigated by effective responses to health-harming legal needs.[7]

Medical-legal partnerships respond to these needs and consequently have been able to demonstrate improvements in outcomes.[8] Their interdisciplinary framework offers particular benefits:

> Through training, lawyers teach doctors how to "observe the health effects of socioeconomic factors or detect when such factors detract from their patients' care." When such factors are identified, doctors can turn to their legal partner to provide the knowledge, resources and assistance to remove or mitigate adverse circumstances.[9]

By working together, doctors and lawyers, often in partnership with other professional groups, are able to respond more effectively to negative social determinants or health-harming legal needs than either professional group could working alone.

The medical-legal partnership model was developed in the early 1990s to respond to patients' health-harming legal needs and was first implemented in 1993 at Boston Children's Hospital.[10] Since then, hospitals and other healthcare institutions throughout the nation have adopted the model. At the same time, the focus of the medical-legal partnership movement has expanded to respond to the diverse needs of children, adults and specific patient populations, such as patients with cancer or HIV.[11]

In 2007 the American Bar Association resolved to support the development of medical-legal partnerships.[12] By 2019, 333 such partnerships had been formed and were operating in 46 states.[13] They take several forms. Almost a third of them (121, as of early 2019) had been formed between lawyers and general hospitals and/or health systems. Others were operating in health centers funded through the federal Health Resources and Services Administration[14] (98), children's hospitals (33), veterans affairs medical centers (25), and other healthcare settings (56).[15] Moreover, the majority of existing medical-legal partnerships include health organizations that partner with legal services agencies or academic law clinics.[16] About one-third of the healthcare facilities that participate in medical-legal partnerships have included funding for the partnerships' work in their budgets.[17]

Hofstra/Northwell Medical-Legal Partnership

In the fall of 2018, the Maurice A. Deane School of Law at Hofstra University ("Hofstra") and the Northwell Health System ("Northwell") joined the medical-legal partnership movement, integrating Hofstra attorneys and supervised law students within three of Northwell's outpatient medical clinics. Hofstra, founded in 1935, is situated on 240 acres in Hempstead, New York (Nassau County) about 25 miles east of New York City. The University is private and nonsectarian. Hofstra has almost 140,000 alumni.[18] Northwell, the largest clinically integrated health system and largest private employer in New York State, includes more than 20 hospitals and almost 750 outpatient facilities.[19] Northwell Health Physician Partners[20] provide healthcare in more than 100 medical specialties.[21]

The Hofstra/Northwell Medical-Legal Partnership identifies and

addresses the health-harming legal needs of patients at Northwell. Most live in Nassau and Queens Counties in New York State,[22] and most of the patients enrolled in the partnership are Medicaid-eligible or uninsured. The partnership's mission calls for delivering legal services in a number of essential areas to clinic patients and to their immediate family members.

In 2018, the general pediatric practice in the outpatient Northwell pediatric clinic (one of the clinics in which the Hofstra/Northwell Medical-Legal Partnership operates) had a caseload of over 12,000 patients in 2018 and averages more than 40,000 visits each year. (All of the data presented in this paragraph come from Northwell records.) Approximately two-thirds of these patients received healthcare coverage through Medicaid or Medicaid managed-care plans. The other Northwell clinics that are served by the medical-legal partnership are general internal medicine clinics (providing outpatient care to patients at least 18 years of age). The larger of the two adult clinics averages more than 26,000 patient visits annually. About 40 percent of the patient population using this clinic receives coverage through Medicaid or is uninsured. About 70 percent of the patients who use the smaller of the two adult clinics (with approximately 5,000 patient visits annually) is covered by Medicaid or is uninsured. Each of the Northwell clinics (one pediatrics and two internal medicine) in which the medical-legal partnership operates has a large team of professionals that includes doctors, nurses, social workers, a psychologist, and now attorneys.

Patients who screen positive for health-harming legal needs are referred by the medical-legal partnership's patient navigators to social workers or to medical-legal partnership attorneys. The navigators have been trained to identify which resources and/or profession can best address a patient's needs. The legal services – following the model of the National Medical-Legal Partnership – now include "income supports" (helping patient-clients gain access to public benefits to which they are entitled); housing (helping patient-clients find and keep habitable housing); education (responding to children's special education needs); employment (responding to discrimination in hiring, promotion and/or firing); and legal status (responding to the immigration needs of undocumented immigrants).[23]

Each medical-legal partnership faces a series of challenges as it constructs how best to serve its patient-client population. This article explores three challenges – and the lessons learned from them – that arose in the early months (late 2018 through the first five months of 2019) after implementation of the Hofstra/Northwell Medical-Legal Partnership in October 2018. It describes responses to those challenges that have been or are being constructed by the medical-legal partnership's interdisciplinary team,[24] including attorneys and physicians, as well as social workers, patients, patient navigators, and administrators. It also describes some persistent stumbling blocks with which the medical-legal partnership continues to struggle. It explores each of these challenges and the medical-legal partnership's evolving responses to them.

The first challenge concerns screening. Screening is essential to identify medical-legal partnership patients. Each medical-legal partnership needs an effective and compassionate method for screening patients for health-harming legal needs that allows non-professionals (patient navigators) to identify patients in need of social or legal assistance. The screening tool also helps the patient navigators to distinguish between patients needing assistance from social workers associated with the outpatient clinics and those needing assistance from attorneys or other resources. Initially, the partnership leveraged the structure and content of a pre-existing screening tool, administered by patient navigators working in the clinics for several years before creation of the medical-legal partnership. Through that tool, navigators have identified clinic patients with health-harming social and legal needs.[25] That screening tool offered a very useful model. In order to serve the medical-legal partnership's patient-clients as effectively as possible, the screen has undergone several quality improvement cycles.

A second challenge has been patient-client engagement. That challenge was occasioned by the search for a better method of engaging patients in need of legal assistance. At the same time, the medical-legal partnership has struggled to identify reasons that patients decline the legal help that the partnership offers to them and to respond to patterns of patient refusal through education and changes in protocol. These concerns require construction of approaches that decrease the stigma, and even fear, that clinic patients have sometimes associated with seeking legal help.

Third, the medical-legal partnership has struggled and continues to struggle with information sharing among professionals. There are several limitations on sharing information about patients and clients without overstepping the partnership's agreements, violating federal and state laws or compromising attorney-client privilege.

Challenges and Developing Responses

The Hofstra/Northwell Medical-Legal Partnership team has identified and addressed the three challenges: screening, patient-client engagement, and information sharing, with varying levels of success. The partnership has constructed a successful response to the first challenge. The second challenge is being addressed through a set of institutional responses that have not yet been fully implemented. And

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the third continues to present unresolved concerns and questions.

Screening Patients for Health-Harming Legal Needs

Medical-legal partnerships are only as effective as their capacity to identify patients with health-harming legal needs. In many medical-legal partnerships, trained physicians, including residents, and social workers screen patients for possible referral to attorneys.[26] That approach has proven impractical for the Hofstra/Northwell Medical-Legal Partnership because of the high volume of patients using the clinics in which the partnership operates. Thus, the partners decided to rely on the patient navigators who were already working in the clinics and were identifying patients with social needs. Partnership physicians and attorneys educated the navigators about the scope and goals of the partnership, providing them with comprehensive information about health-harming legal needs and about distinctions between those needs and needs to which hospital social workers can best respond. By early 2019, patient navigators at the Northwell clinics in which the medical-legal partnership operates had screened about 2,000 clinic patients. About half screened positive for at least one adverse social determinant of health and about 10 percent screened positive for health-harming legal needs. Most patients who screened positive for social and/or legal needs presented with multiple needs. However, almost one-third of those screening positive after the initial intake did not complete the process that would lead to referral to a lawyer and have thus not received legal assistance.[27]

In addition to the screening tools developed before creation of the medical-legal partnership by several physicians at Northwell, the Hofstra/Northwell partners have worked to augment a data capture system available to all partners. This has facilitated navigators' success in determining which patients have health-harming needs best addressed by social workers and which patients would be best served by referral to an on-site attorney. The intake process is handled differently should a patient present with an emergent legal need such as a threatened deportation or eviction. Patients with potentially serious and emergent legal needs are offered the opportunity to meet immediately with an on-site attorney.

Augmentation of the data capture system[28] has involved development of a triage algorithm that assists navigators in identifying patients' social and legal needs and in distinguishing between them. The algorithm features a branching logic that directs navigators to subsequent questions in light of patients' responses to early questions. In short, a patient identified on initial screening as having a potential social or legal need is guided through a series of follow-up questions that "unlock" subsequent questions or algorithmic responses.

Navigators' reliance on the branching logic algorithm for screening patients has proven to be efficient.[29] In the first five months of the medical-legal partnership's operation, navigators using branching logic identified scores of patients with health-harming legal needs that have spanned the panoply of legal needs for which partnership attorneys offer assistance. On-site attorneys consulted with a majority of these patients. About 52 percent of the patients with whom medical-legal partnership lawyers were able to make a connection received substantive legal services from attorneys and the law students working under attorney supervision.

Use of questions embedded in the branching logic tool have resulted in few false positives. In addition to facilitating navigators' identification of patients in need of legal services, the tool has proved valuable to attorneys and clients during initial consultations. In particular, attorneys have been able to formulate more probing, directed questions at the start of client consultations than would otherwise have been possible.

Despite the usefulness that the algorithm has had for patient screening, a number of constraints continue to limit the tool's success in helping to screen patients. The medical-legal partnership is responding actively to these constraints. First, the effectiveness of the screening tool is curtailed if navigators do not proceed through the full set of questions dictated by the tool's branching logic. That does not always happen, in part because conversations between navigators and patients are guided by the natural flow of language. That flow can interrupt navigators' focus on questions that would have been suggested by the algorithmic tool which, in comparison to natural language, can seem robotic to the navigators and to the patients. This stumbling block can probably not be remedied completely because the preservation of natural conversation is essential to the development of a comfortable patient-navigator relationship. The Hofstra/Northwell Medical-Legal Partnership can, however, ensure that navigators are aware of methods for completing the algorithm's branching logic while allowing for empathic interaction with patients.

Second, the algorithmic tool has proven problematic for patients with immigration issues. Legal challenges for undocumented patients are often serious and emergent. Furthermore, patients may be hesitant to discuss concerns about their legal status. The Hofstra/Northwell Medical-Legal Partnership has thus designed the

branching logic in this domain so that it captures almost everyone with any sort of immigration issue. That is to say, the partnership has chosen a logic that over-screens patients for immigration issues rather than risk missing patients who do have emergent immigration problems. Each of the cases in which a patient is identified as having any sort of immigration problem is referred to an attorney, but many of those patients might have been referred more productively to social workers.[30]

As a general matter, the branching logic tool facilitates the identification of legal issues as a category of social needs. In the future, Hofstra/Northwell Medical-Legal Partnership doctors and lawyers would also like to be able simultaneously to identify legal needs through reference to medical diagnoses. The paradigmatic example of this sort of reference is the suggestion that the home of a child with asthma should be surveyed for toxins that exacerbate the condition. This sort of reference reflects the medical-legal partnership's goal of providing holistic, integrated services to patient-clients. To meet that goal, the Hofstra/Northwell Medical-Legal Partnership hopes to develop a companion tool that will facilitate identification of legal needs directly from codes for certain medical diagnoses. Moreover, this might be done in conjunction with hospital lists used to identify and remind patients who have not kept routine appointments (e.g., for annual check-ups, mammograms).

Responding to Patients' Reluctance to Seek Legal Assistance

A second challenge, sometimes manifest during screening or thereafter, reflects patients' reluctance to accept legal assistance. This reluctance is reflected in patients' hesitation about engaging with attorneys initially. It is also reflected in patients' concerns about moving forward with legal representation after health-harming legal needs have been identified and a meeting with a medical-legal partnership attorney has been scheduled. In short, patients told that they are eligible for free legal assistance with the goal of resolving or mitigating a health-harming legal need do not always accept that offer. Furthermore, some patients decline to proceed with legal representation after an initial consultation with a medical-legal partnership attorney.

Preliminary, largely anecdotal data collected by physicians at the medical-legal partnership clinics suggest that this reluctance reflects stigma associated with the need for legal help, and, correlatively stigma associated with some of the indicia of socioeconomic status. For undocumented immigrants, that stigma is compounded by the fear that an attempt to gain legal status may result, instead, in deportation. Similar anxieties may affect the parent of a pediatric patient who hesitates to discuss problems with housing for fear that he or she could be identified as neglectful or fearful that addressing the housing problems could backfire, leading to eviction or retaliation by a landlord. Accordingly, the partnership is working on two fronts. It is working to enhance communication channels (1) between navigators and patients and (2) between attorneys and clients. This will facilitate more successfully explaining the work of the medical-legal partnership to patients and in addition, it will help patients feel safe and comfortable working with attorneys. Despite those efforts, not all patients with health-harming legal needs will want to engage medical-legal partnership lawyers. Such refusals from informed patients must be respected.

The first concern – how best to explain our work to patients with health-harming legal needs so as to engage patients and build trust – has raised three practical questions: Who is best situated to deliver information about the medical-legal partnership's legal resources to patients? What information should be delivered? And what is the most effective tool for delivering this information? The partnership expects to work on several levels, at least initially, in identifying who should speak with patients about legal resources. The medical-legal partnership, as such, plans to promote its services in public spaces, including town libraries, through workshops and information sessions. Further, within the medical-legal partnerships clinics, enhanced education about the partnership's work, provided by the patient navigators, social workers, and care coordinators may increase success in effectively communicating information about the help that partnership attorneys can offer to the clinics' patients.

New modes of navigator training may also situate patient navigators more effectively to ease patients' anxieties about accepting legal help and will offer a successful response to our second concern (ensuring that patients feel comfortable talking with navigators, and then with lawyers, about health-harming legal needs). Two Northwell physicians[31] (each of whom played a central role in developing the pre-medical-legal partnership screening tool) plan to implement "empathic inquiry training" for patient navigators at Northwell. It is expected that this training will broaden navigators' communication skills and effect more trusting relationships with patients. These changes should increase patient engagement. Correlatively, it is expected that those patient-clients who are privy to empathic inquiry communication will more readily accept advice from physicians and from medical-legal partnership attorneys than other medical-legal partnership patient-clients.[32]

Communication Among Professionals and Limitations on Data Sharing

The third medical-legal partnership challenge addressed in this

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article concerns constraints on sharing information about patients and clients between partners – that is, between those affiliated with Northwell (e.g., clinicians, social workers, hospital administrators) and those affiliated with Hofstra (e.g., lawyers and students under the supervision of lawyers). The extent of data sharing is an important area of concern for all medical-legal partnerships.[33] Decisions about data sharing help determine the shape of a medical-legal partnership. Among the challenges the Hofstra/Northwell Medical-Legal Partnership has faced, this one is proving more resistant to resolution than others.

Sharing data is not essential. The legal arm of a medical-legal partnership can work independently of the medical arm, much as a law firm working for a hospital might. Some medical-legal partnerships have opted for a separation of services. Clinicians can refer patients to medical-legal partnership lawyers who then provide legal services. This organizational form does not assume the delivery of holistic, integrated services.

Indeed, limits on data sharing become increasingly important the more the medical-legal partnership's physicians and lawyers aim to provide holistic care to patient-clients. The difference between medical-legal partnerships that focus on this goal and those that do not can be analogized to the difference between interdisciplinary and multidisciplinary teams.[34] Challenges occasioned by limitations on sharing data have arisen for the Hofstra/Northwell Medical-Legal Partnership insofar as partners have been reluctant to preclude the benefits assumed to accrue to patients and clients from holistic, integrated care.[35] More research is needed on the comparative value to all medical-legal partnership participants (especially patient-clients) of medical-legal partnerships that function through organizational separation, relying on a multidisciplinary approach to the partnership, and those that function through reliance on an interdisciplinary frame. At this time, the Hofstra/Northwell Medical-Legal Partnership is committed to an interdisciplinary perspective. But that could change in light of research findings or in response to shifts in the medical-legal partnership's procedural goals.

In any event, concerns about data sharing are more complicated with regard to the sharing of electronic data than the sharing of other forms of data. Even information shared during in-person conversations can raise problems. However, these problems can be resolved more easily than problems occasioned by sharing electronic data and will thus be considered first.

In particular, patient information can only be shared if patients, informed about the consequences of sharing data, agree to that. Yet, even if patients agree to data sharing, the participation of third parties in client-attorney conversations may interfere with attorney-client privilege. That privilege protects client communications with attorneys from being revealed in court or in other legal settings.[36] The risk that the privilege could be obviated because of the participation of a patient's physician or other clinician in a meeting with the patient's medical-legal partnership lawyer can be mitigated by formally designating the medical participant as a member of the client's legal team.[37] The medical professional's participation may be useful in helping explain how the social determinants of health affect a client's health problems. That provides justification for designating the clinician as a member of the legal team, at least for purposes of participating in specific attorney-client meetings without significant risk of losing the attorney-client privilege.[38]

In contrast, information and communications saved in electronic form cannot be shared within the Hofstra/Northwell Medical-Legal Partnership regardless of patient consent. Arrangements between the two institutions composing the partnership (Hofstra and Northwell) preclude sharing electronic data across institutional boundaries. There are good institutional reasons for caution about sharing data, and this preclusion is not unique to the Hofstra/Northwell Medical-Legal Partnership. Among other things, as discussed above, attorneys are concerned about protecting attorney-client privilege, and hospital systems and other healthcare organizations are concerned about abiding by rules regarding data sharing and privacy. Limitations on hospitals' sharing information reflect federal and state[39] laws, including the privacy protections that followed promulgation of the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA").[40] Privacy law, in general, imposes stricter limitations on hospitals and healthcare professionals than on universities.

More specifically, the legal arm of the medical-legal partnership relies on CLIO, a cloud-based legal management system. The medical arm of the partnership relies on an electronic medical record ("EMR") for recording information about patient care. These systems are not integrated. All data recorded in either is protected from access by those using the other system. This separation, though perhaps unavoidable in light of institutional concerns, limits the capacity of the medical-legal partnership to develop a holistic approach to care. Such an approach would seem clearly to depend on the possibility of sharing data. Further, constraints on sharing data complicate assessments of the work of the medical-legal partnership.

Again, these problems would diminish in the context of a multidisciplinary partnership that did not aim to provide holistic care.

Were the partners to the Hofstra/Northwell Medical-Legal Partnership able to share electronic data across institutional boundaries, waivers on which they now rely in sharing non-electronic data (e.g., in the course of attorney-client communications) would become necessary. These include HIPAA waivers of authorization[41] and waivers of attorney-client privilege. Those options raise significant questions in their own right, questions that cannot responsibly be elided, but they are relevant to shared data in electronic or non-electronic form.

As a technical matter, the medical-legal partnership's legal and medical data could be integrated and shared through a hospital "dashboard" that brings a number of data sources (e.g., population health information; claims information) together. Such a dashboard could also include legal data, providing the partnership with an integrated approach to data analysis. This option is not available to the Hofstra/Northwell Medical-Legal Partnership, of course, since at present the two institutions are precluded from sharing any electronic data across institutional boundaries. An alternative approach might be the creation of a data "clean room" – a common place in which aggregated data (but not data about individual patient-clients) is shared. The partnership continues to consider how best to deliver holistic care to its patient-clients in light of constraints on sharing data. Its responses look to interdisciplinary education and robust communication among the medical-legal partners concerning the partnership's over-arching goals and the best processes through which to reach those goals. In the future, it is possible that The partnership will replace its vision of an interdisciplinary medical-legal partnership with that of a multidisciplinary organization. Should that happen, data sharing would be of decreasing concern to the partnership's participants.

Additional Challenges

In addition to the challenges discussed above, the Hofstra/Northwell Medical-Legal Partnership is responding to a slew of other conundrums that face many medical-legal partnerships. These provide fodder for future articles. Such challenges include ensuring the partnership's sustainability; broadening the focus of the partnership's legal services; involving physicians, nurses, and social workers not initially identified with the work of the medical-legal partnership; and expanding work beyond the partnership's initial clinic settings, both into more specialized clinics and into the community (including, for instance, schools and prisons).

A challenge of particular importance – but one beyond the scope of the present article – has been occasioned by confusions that can arise among professionals aware of and committed to dissimilar codes of professional ethics.[42] The medical-legal partnership movement has responded with sample Memoranda of Understanding and online courses that outline challenges faced by professionals committed to distinct professional codes.[43]

Creation of a new, supplemental professional code of ethics, appropriate for interdisciplinary work among medical clinicians and lawyers, might focus on shared components of professional identity as well as on components that may not be amenable to sharing but that, as such, should compel each professional group to understand the other group's professional assumptions.[44]

The professionalization of hospital chaplains offers a model.[45] Focusing on the need for professional accountability, one author recommends that new professional groups such as hospital chaplains delineate their group's core functions and distinguish those functions from the core functions of other groups working within the hospital setting. In the context of a medical-legal partnership, each professional partner should be able to understand his or her professional identity within the context of the partners' professional identities. An additional recommendation calls for the delineation of a "standard of quality" and a method for assessing its actualization or not. An ethics code for those working together in medical-legal partnerships would need to define a standard of quality for effecting and assessing the partnership's interdisciplinary work.[46]

Conclusions and Lessons Learned

The challenges discussed in this article, though specific to medical-legal partnerships, suggest a wider set of challenges facing attorneys involved in various forms of multidisciplinary and interdisciplinary work.[47] Such collaborative work can be productive. Thus, some of what has been learned from challenges that have arisen in the course of planning and implementing the Hofstra/Northwell Medical-Legal Partnership can be usefully translated into helpful guidance for other health lawyers who work actively with clinicians, social workers, psychologists and members of other professional groups. Education about the goals and processes of multidisciplinary or interdisciplinary work is essential. Educational programs must be shaped in light of the goals and needs of specific collaborative efforts. The Hofstra/Northwell Medical-Legal Partnership has focused on educating clinicians (including, especially, residents), lawyers, social workers, patient navigators, patients, clients, and students from the University's schools of law and medicine about the social determinants of health and the significance of the work of the medical-legal partnership for patients from vulnerable populations, and its significance for medical

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clinicians and attorneys privileged to engage in work that promises to increase the health and welfare of vulnerable populations.

Every medical-legal partnership is unique. Some have involved affiliations between health organizations and academic institutions. Others have involved affiliations between health organizations and legal aid societies. Some offer a wide array of legal services; others offer more limited services. Among medical-legal partnerships, the distribution of duties and obligations among professional participants can differ significantly. In addition, sources of medical-legal partnership funding differ from partnership to partnership.[48]

Yet, all medical-legal partnerships must focus on teaching professionals to cooperate as team members, and those that aim to work in an interdisciplinary fashion must focus as well on abandoning professional silos. Most important, all medical-legal partnerships strive to improve the health of individuals and populations by identifying and responding to the social determinants of health and to health-harming legal needs. In doing this, many medical-legal partnerships have faced the sort of challenges delineated here.

Specific solutions to those challenges must be crafted in light of the institutional identity of each medical-legal partnership's participants, the scope of the partnership, and the social determinants most likely to affect the health of the medical-legal partnership's patient-client population. Some goals are shared among all medical-legal partnerships. A successful medical-legal partnership assumes the ability of physicians and lawyers to understand each other's concerns and obligations and to cooperate in re-shaping their assumptions in the service of the partnership's patients and clients. A case study of a large and successful medical-legal partnership between NYC Health + Hospitals and LegalHealth stresses the importance for any medical-legal partnership of "establish[ing] open communications and means of collaboration" between doctors and lawyers at the start.[49] Further along, the Hofstra/Northwell Medical-Legal Partnership hopes to report, as has that created between the NYC Health + Hospitals and LegalHealth, that its work has demonstrated a good "financial return on investment."[50] This suggests that medical-legal partnerships are effective in serving the "triple aim": at once, they improve patients' experiences with healthcare, serve population health, and decrease the cost of healthcare, per capita.[51]

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Endnotes

1 *See* Bradley Sawyer & Cynthia Cos, Peterson-Kaiser Health System Tracker, How Does Health Spending in the U.S. Compare to Other Countries, Dec. 7, 2018, https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-start (last visited May 23, 2019) (reporting that in 2017, the United States spent $10,224 per capita on healthcare. That was 28% higher than Switzerland, the second highest spender).

2 Nat'l Cent. For Medical Legal Partnership, The Need, *available at* https://medical-legal-partnership.org/need/ (last visited March 17, 2019). In the United States more is spent on healthcare than on social services. "Other first-world countries with better outcomes" spend more than twice as much on social services as they spend on healthcare. *Id.* Yet, among nations, the United States ranks 42nd in life expectancy and 169th on low birth weight. *Id.*

3 Elizabeth Tobin Tyler, Introduction xxxi in Poverty, Health and Law: Readings and Cases for Medical-Legal Partnership (Elizabeth Tobin Tyler & Ellen Lawton, et al., eds. 2011) (hereinafter "Tyler & Lawton"); Steven A. Schroeder, We Can Do Better – Improving the Health of the American People, 357 (12) N.E.J.M. 1221 (2007). *See also* Approaches to Cross-Sector Population Health Accountability (Discern Health for Academy Health) (last visited May 29, 2019) (reporting that "[o]nly 20 percent of a person's health and well-being is attributed to clinical care, compared to 80 percent attributed to social, behavioral and environmental factors") (footnote omitted), https://www.academyhealth.org/sites/default/files/Approaches_to_CrossSector_Pop_Health_Jan2018_0.pdf (last visited May 29, 2019).

4 Wendy E. Parmet, Lauren A. Smith, & Meredith A. Benedict, Social Determinants, Health Disparities and the Role of Law in Tyler & Lawton, *supra* note 3, at 4 (citing World Health Organization, *Closing the Gap in a Generation: Health Equity through Action on the Social Determinants of Health* (2008)).

5 Michael Marmot, The Status Syndrome: How Social Standing Affects Our Health and Longevity 41-43 (2004).

6 National Medical-Legal Partnership (Home), https://medical-legalpartnership.org/ (reporting that the United States spends 90 cents on social services for every dollar that it spends on healthcare; nations with better health outcomes spent about twice what they spend on healthcare on social services) (last visited May 23, 2019) (referring to research from The American Health Care Paradox (2015) by Elizabeth Bradley & Lauren Taylor).

7 Marmot, *supra* note 5, at 6-7.

8 National Center for Medical-Legal Partnership, Impact, https://medical-legalpartnership.org/impact/ (last visited June 11, 2019) (noting less frequent hospital admissions for people with chronic disease, greater adherence to medication schedules, less stress and better mental health, among other things).

9 *See* Randye Retkin, Julie Brandfield, & Margo Hoppin, Medical Legal Partnerships: A Key Strategy for Mitigating the Negative Health Impacts of the Recession, 22 Health Lawyer 29 (Oct. 2009).

10 Elizabeth Tobin Tyler, Introduction xxxi-xxxii in Tyler & Lawton, *supra* note 3.

11 *Id.* at xxxii.

12 Retkin, Brandfield & Hoppin, *supra* note 9. The following year, the ABA implemented a Medical-Legal Partnership Pro Bono Support Project. *Id.*

13 National Center for Medical-Legal Partnership (Home), https://medical-legalpartnership.org/ (last visited May 23, 2019). State support is also important. In 2013, New York State amended its Public Health Law ("PHL") to allow legal entities to register as "Health-Related Legal Services Programs." Standards for Health-Related Legal Services Programs that Serve Income Eligible Individuals and Families Pursuant to PHL Section 22 (Dept Health, NYS), https://ealth.ny.gov/diseases/aids/providers/regulations/standards_for_health_related_legal_services_prog.htm; *see also* Nat'l Center for Medical-Legal Partnership, New York Law Recognizes MLPs (2013), https://medical-legalpartnership.org/new-york-law-recognizes-mlps/.

14 The Health Resources & Services Administration ("HRSA") is an agency within the Department of Health and Human Services. It is dedicated to "improving health care to people who are geographically isolated, economically or medically vulnerable". HRSA, https://www.hrsa.gov/about/index.html (last visited June 30, 2019).

15 Nat'l Cent. For Medical-Legal Partnership, Partnerships, *available at* https://medical-legal-partnership.org/ (last visited March 17, 2019).

16 *Id.*

17 Marsha Regenstein, Jennifer Trott, & Alanna Williamson, Report: Findings from the 2016 NCMLP National Survey on MLP Activities and Trends, Nat'l Centr. For Medical-Legal Partnership (Aug. 3, 2017), *available at* https://medical-legalpartnership.org/mlp-resources/2016-ncmlp-survey-report/ (last visited March 17, 2019).

18 https://www.hofstra.edu/about/about_glance.html# (last visited May 23, 2019).

19 Northwell is the 14th largest healthcare system in the nation, https://www.northwell.edu/about-northwell (last visited May 23, 2019).

20 Northwell Health Physician Partners includes all physicians affiliated with Northwell. Northwell Health Physician Partners, Northwell Health, https://www.northwell.edu/physician-partners (last visited June 30, 2019).

21 https://www.northwell.edu/about-northwell (last visited May 23, 2019).

22 Nassau County is one of two counties on Long Island not part of New York City. Queens County is part of New York City.

23 These services reflect the health-related categories of legal service that have been identified by the National Center for Medical-Legal Partnership. They are known by the acronym I-HELP. The "P" in I-HELP refers to personal and family matters. *See, e.g.,* Ellen Lawton et al., Medical-Legal Partnership: A New Standard of Care for Vulnerable Populations 71 in Tyler & Lawton, *supra* note 3, at 75, 113. The Hofstra/Northwell Medical-Legal Partnership does not now, but soon hopes to, provide legal representation in this area.

24 The Hofstra/Northwell Medical-Legal Partnership's educational programs aim to transform multidisciplinary work into interdisciplinary work. Multidisciplinary teams include people trained in various disciplines who work within their disciplinary frameworks. Interdisciplinary work relies on shared knowledge and assumptions that, when most effective, creates a "coordinated and coherent whole." *See* B.C. Choi & A.W. Pak, Multidisciplinarity, Interdisciplinarity and Transdisciplinarity in Health Research, Services, Education and Policy, 29 Clin. Invest. Med., 351, Dec. 2006, https://www.ncbi.nlm.nih.gov/pubmed/17330451.

25 The navigator program, started in 2016, has operated since that time in two of Northwell's ambulatory clinics. The medical-legal partnership, which began its work two years later, has broadened the screen to include legal (as well as social needs) and to distinguish between clinic patients' social and legal needs. As a practical matter, this often involves distinguishing among patients whose needs can be met by social workers and those whose needs require attorney assistance.

26 Jennifer Trott, Medical Legal Partnership Measurement Series, Issue Brief One, Screening for Health-Harming Legal Needs, https://medical-legalpartnership.org/wp-content/uploads/2016/12/Screening-for-Health-Harming-Legal-Needs.pdf (last visited July 3, 2019).

27 The reasons for this are multiple. Some patients declined the opportunity to receive legal assistance; some misunderstood the question; and some missed appointments, among other reasons.

28 RedCAP intake forms are shared, but not in electronic form. While arrangements between Northwell and Hofstra preclude sharing electronic data, paper copies of RedCAP intake forms can be shared.

29 The algorithm was also created to be cost-effective. However, the medical-legal partnership does not yet have data about its cost-effectiveness.

30 Unfortunately, there is often little that social workers or attorneys can do at this time to help patients with undocumented immigration status.

31 One of these physicians is a co-author of this article.

32 Medical-legal partnership physicians will study the effectiveness of empathic inquiry training for patient navigators by comparing outcomes, including patient utilization of

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healthcare; patient-reported health; navigator effectiveness; and identification of social-determinants of health among patients screened by navigators with empathic inquiry training and patients screened by navigators without that training.

33 Janet Hyatt Thorpe et al., Information Sharing in Medical-Legal Partnerships: Foundational Concepts and Resources (Medical-Legal Partnership Fundamentals, 2017), https://medical-legalpartnership.org/wp-content/uploads/2017/07/Information-Sharing-in-MLPs.pdf.

34 See *supra* note 24 (describing difference between interdisciplinary and multidisciplinary work).

35 Data-sharing within a medical-legal partnership is not an "all or nothing" matter. Certainly, healthcare practitioners and legal service providers often share patients' names and contact information as part of a routine referral for services. Consideration of the level and type of information shared within a medical-legal partnership always involves attention to nuance.

36 Paula Galowitz et al., Ethical Issues in Medical-Legal Partnerships in Tyler & Lawton, *supra* note 3 at 166.

37 Galowitz et al., *supra* note 36, at 166.

38 *Id.* The authors strongly suggest that despite this justification for participation of a medical professional in a meeting between a patient-client and his or her medical-legal partnership attorney, the attorney obtain an informed waiver of privilege from the client. *Id.* Clients should be made aware of the implications of losing attorney-client privilege.

39 State laws that offer greater protection than that afforded by HIPAA, *see* note 40, *infra*, are not preempted by the federal law and may impose additional limitations on sharing protected health information. *Id.* at 167.

40 The Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936; *see* 45 C.F.R. Parts 160, 162, & 164 for regulations about privacy. *See also* The Health Information Technology for Economic and Clinical Health ("HITECH") Act, enacted under the American Recovery and Reinvestment Act of 2009, Div. A, Title XIII of Pub. L. 111-5.

41 Hofstra/Northwell Medical-Legal Partnership patient-clients now sign HIPAA waivers that allow partnership attorneys to discuss a patient's medical situation with the patient's physician.

42 An interesting example of such differences is attorney-client privilege, which is without a counterpart in the physician-patient relationship. As a result, physicians are sometimes baffled when lawyers invoke privilege claims. *See* Galowitz, *supra* note 36, at 166.

43 Charley Connor, The Benefits of Medical-Legal Partnerships for Low-Income Families, 8 Wake Forest J.L. & Pol'y 193, 209 (2018). HIPAA protects "individually identified health information." 45 C.F.R. §§ 160.103, 164.501.

44 Margaret Mohrmann has discussed a new ethic for chaplains that is intended to supplement, not replace, existing ethical guidelines. Margaret E. Mohrmann, Ethical Grounding for a Profession of Hospital Chaplaincy, 38 *Hastings Center Report* 18 (Nov. – Dec. 2008).

45 *Id.*

46 Two of the co-authors of this article intend to draft the provisions that such a supplemental code of ethics might contain.

47 See *supra* note 24 (describing difference between the two approaches).

48 Jennifer Trott, Alanna Peterson & Marsha Regenstein, Financing Medical-Legal Partnerships: View from the Field, Medical-Legal Partnership Fundamentals: Issue Brief Two, p. 4 (April 2019), https://medical-legalpartnership.org/wp-content/uploads/2019/04/Financing-MLPs-View-from-the-Field.pdf. Some medical-legal partnerships are funded by the healthcare organization within which they operate. Others receive funding from legal organizations, and still others rely at least in some part on philanthropic donations.

49 Joanna Theiss, Janelle Schrag & Joel Teitelbaum, A System-Level Approach to Addressing Health-Harming Legal and Social Needs (National Center for Medical-Legal Partnership), https://medical-legalpartnership.org/wp-content/uploads/2019/04/A-System-Level-Approach.pdf.

50 *Id.* at 12.

51 Institute for Healthcare Improvement, IHI Triple Aim Initiative, http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx (last visited on May 23, 2019). The triple aim was described by Donald M. Berwick in 2008. Donald M. Berwick et al., The Triple Aim: Care, Health, and Cost, 27 Health Aff. 759 (2008). Berwick served as the Administrator of the Centers for Medicare & Medicaid Services under President Obama. Profiles in Leadership: Don Berwick, Institute for Health Improvement, http://.ihi.org/education/ihiopenschool/resources/Pages/ProfilesInLeadershipDonBerwick.aspx (last visited June 30, 2019). Commentators noted that "[a]lthough the triple aim originally focused primarily on the integration of clinical care . . . , it is now accepted that integration sectors that impact public health and medical care will be key to improving population health. James Teufel et al., Rural Health Systems and Legal Care: Opportunities for Initiating and Maintaining Legal Care After the Patient Protection and Affordable Care Act, 35 J. Leg. Med. 81 (2014).

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