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INSIDE:

The Practical Impact of the Medicare Secondary Payer Act

By John H. Ruiz and Frank C. Quesada[1]

The Medicare Act has been described as "one of the most completely impenetrable texts within the human experience".[2] If that seems daunting, at least the Medicare Secondary Payer Act has only been described as "tortuous."[3] This article analyzes the Florida judiciary's interpretation of this Medicare gauntlet.

A. Background

At its inception, Medicare was the primary payer for medical treatment of its beneficiaries except in limited instances. In 1980, Congress enacted the Medicare Secondary Payer Act ("MSPA") in an effort to counteract the rapid depletion of the Medicare Trust Fund by increasing the number of coverage and benefit programs that are primary to Medicare's payment obligations.[4] In other words, Medicare was no longer responsible for paying its beneficiaries' claims when payment was available from a "primary plan." Primary plans include workers' compensation plans, group health plans, liability insurance policies or plans (including a self-insured plan or tortfeasor) and no-fault insurance.[5] The MSPA prohibits Medicare from making payment if payment has been made, or can reasonably be expected to be made promptly, by a primary plan.[6] However, if payment has not been made or cannot be expected to be made promptly by a primary payer, Medicare, as a secondary payer, may make a conditional payment.[7] Secondary payments are made subject to reimbursement from the primary plan's payment.[8]

Medicare Advantage Organizations ("MAOs") are also secondary payers under the MSPA. Section 1395w-22(a)(4) in Part C of the Medicare Act, titled "Organization as secondary payer" specifically cross-references the MSPA and provides that "[n]otwithstanding any other provision of law," MAOs may charge primary plans, or their own enrollees, to recover reimbursement of secondary payments "under circumstances in which payment under this title is made secondary pursuant to section 1395y(b)(2) of this title."[9] Moreover, CMS regulations require MAOs to identify all primary payers, identify any amounts payable by those payers, coordinate benefits to Medicare enrollees with the benefits provided by primary payers, and seek reimbursement directly from the primary plan, or from enrollees to the extent they have received payment from a primary payer.[10] With the expansion of Medicare, this structure established MSPA provisions that are consistent for Medicare enrollees and providers. Importantly, since MAO premiums are paid by CMS, the secondary payer requirements help manage the demands on the Medicare Trust Fund and limit Medicare's overall costs.

B. Primary Payers and Coordination of Benefits

Pursuant to 42 U.S.C. § 1395y(b)(2)(A), Medicare is secondary to any "primary plan" obligated to pay a Medicare recipient's medical expenses. Primary payers under the MSPA consist largely of three categories: 1) general liability insurance, 2) no-fault insurance, and 3) worker's compensation insurance. A primary plan's responsibility to pay may be demonstrated "by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means."[11] Further, the Code of Federal Regulations and CMS' Medicare Secondary

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CMS Issues Final 60-Day Rule for Medicare Overpayments

By Lani M. Dornfeld, Esq.[1]

When the Affordable Care Act was enacted in March 2010, section 6402(a) enacted Section 1128J(d) of the Social Security Act (the "Act") requiring a person[2] who receives an overpayment[3] of Medicare or Medicaid payments[4] to report and return the overpayment, with written notice as to the reason for such overpayment, to the Secretary of the Department of Health and Human Services ("DHHS"), the state, an intermediary, a carrier, or a contractor, as appropriate, at the correct address. On February 12, 2016, DHHS published its final rule (the "Final Rule") implementing the requirements of the Affordable Care Act.[5] The Final Rule became effective on March 14, 2016. As this article will explain, the statute and Final Rule are broad and create new authority for the federal government to place the responsibility to report federal health care program fraud, waste, and abuse squarely on the shoulders of providers and suppliers. If enforced aggressively, there are few providers and suppliers the Final Rule will not impact.

The 60-Day Rule: Overview

Section 1128J(d)(2) of the Act requires an overpayment be reported and returned by the later of: 1) the date which is 60 days after the date on which the overpayment was identified; or 2) the date any corresponding cost report is due, if applicable. Section 1128J (d)(3) provides that any such overpayment retained after the deadline is an "obligation"[6] for purposes of 31 U.S.C. § 3729 (the False Claims Act), thus creating "reverse false claim" liability.

A person has identified an overpayment when the person knows or should have known, through the exercise of reasonable diligence, that it has received an overpayment and has quantified the amount. The term "knowingly" means that a person 1) has actual knowledge of the information; 2) acts in deliberate ignorance of the truth or falsity of the information; or 3) acts in reckless disregard of the truth or falsity of the information.[7] In other words, an overpayment must be reported and returned regardless of whether it happened because of human error, system error, fraudulent behavior, unintentionally, uncontrollable factors or any other reason, whether seemingly "innocent" or not.[8] Examples of overpayments include Medicare payments for non-covered services, Medicare payments in excess of the allowable amount for an identified covered service, errors and non-reimbursable expenditures in cost reports, duplicate payments and receipt of Medicare payment when another payor had the primary responsibility for payment.[9]

For cost report providers, a payment does not become an overpayment until after costs have been applicably reconciled (cost reporting). Centers for Medicare & Medicaid Services (CMS) has recognized that interim Medicare payments are paid based on estimated costs that are not actually known until a later date when reconciliation takes place. At the point at which costs are "known," an overpayment may be identified. Providers should report related overpayments with their cost report.

The deadline for reporting overpayments will be suspended upon any of the following: 1) DHHS, Office of Inspector General (OIG) acknowledges receipt of a submission to the OIG Self-Disclosure Protocol and will remain suspended until a settlement agreement is entered, the person withdraws from the protocol or the person is removed from the protocol; 2) CMS acknowledges receipt of a submission to the CMS Voluntary Self-Referral Protocol and will remain suspended until a settlement agreement is entered, the person withdraws from the protocol or the person is removed from the protocol; or 3) a person requests an extended repayment schedule and will remain suspended until such time as CMS or one of its contractors rejects the extended repayment schedule request or the provider or supplier fails to comply with the terms of the extended repayment schedule.

Interestingly, DHHS states that the quantification of the amount of the overpayment may be determined by using statistical sampling, extrapolation methodologies and "other methodologies as appropriate."[10]

The Final Rule prescribes the form and manner for reporting and returning an overpayment to include use of an applicable claims adjustment, credit balance, self-reported refund or other reporting process set forth by the applicable Medicare contractor to report an overpayment. Exception is made for disclosures made to and resulting in settlement agreements under the OIG or CMS voluntary self-disclosure protocol.

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Under the Final Rule, the look-back period is six years (rather than the ten years previously anticipated). This means a person must report, quantify, and return overpayments only if a person identifies the overpayment within six years of the date the overpayment was received.

"Reasonable Diligence" and "Credible Information"

Under the Final Rule, the 60-day timer starts 1) when "reasonable diligence" is completed (that is, when the provider or supplier both has determined that it has received an overpayment and has quantified the overpayment), or 2) if the provider or supplier fails to conduct "reasonable diligence," at most six months from the day the provider received "credible information" of a potential overpayment (with two additional months for reporting and returning).[11] Thus, in the absence of extraordinary circumstances, a provider has eight months to investigate, report, and return overpayments once credible information is learned. Notably, the failure to exercise reasonable diligence in the absence of an overpayment does not, in and of itself, expose a provider or supplier to liability. However, despite DHHS's comment that "[c]reating this standard for identification provides needed clarity and consistency for providers and suppliers on the actions they need to take to comply with requirements for reporting and returning of self-identified overpayments,"[12] these concepts create difficult conundrums for providers and suppliers subject to the Final Rule.

According to DHHS, reasonable diligence includes "both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments and investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment." As such, proactive and reactive activities are required, and providers and suppliers are expected to have in place "qualified individuals" to manage these activities.

With respect to proactive measures, DHHS states that "[p]roviders and suppliers are responsible for ensuring their Medicare claims are accurate and proper and are encouraged to have effective compliance programs as a way to avoid receiving or retaining overpayments," and that "undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier's Medicare claims would expose a provider or supplier to liability under the identified standard articulated in [the Final Rule] based on the failure to exercise reasonable diligence if the provider or supplier received an overpayment."[13] Essentially, and although DHHS has recognized that the compliance program of a small provider or supplier, such as a solo medical practice, will be very different from such program in a larger setting, such as a multi-specialty group practice or hospital, the take-away is that providers and suppliers who do not currently have a robust compliance program in place are well-advised to do so immediately.

With respect to reactive measures, DHHS states that timely, good faith investigation of "credible information," is required. DHHS "considered but rejected" adopting a looser standard, such as "reasonable period of time to investigate," and has chosen six months as the benchmark for timely investigation because DHHS believes "that providers and suppliers should prioritize these investigations and also… recognize that completing these investigations may require the devotion of resources and time."[14] Absent extraordinary circumstances, such as unusually complex investigations, natural disaster or state of emergency, a total of eight months (six for investigation and two for reporting and returning), is deemed by DHHS to be sufficient. [15]

"'Credible information' includes information that supports a reasonable belief that an overpayment may have been received."[16] This standard is fact-specific, but should not lead practitioners to investigate every piece of information if that information is not credible enough to support a reasonable belief an overpayment may have been received. Examples of credible information is noticing unusually high profits in relation to time worked or RVUs or receiving a hotline complaint detailed enough to meet the standard. In commentary to the Final Rule, DHHS offered a non-exhaustive list of circumstances when providers must make reasonable inquiry, including when a provider or supplier:[17]

- reviews billing records and learns of incorrect coding of services resulting in increased reimbursement.
- learns that a patient death occurred prior to the service date on a submitted claim for payment.
- learns that services were provided by an unlicensed or excluded individual on its behalf.
- performs an internal audit and discovers that overpayments exist.
- is informed by a governmental agency of an audit revealing a potential overpayment and it fails to make a reasonable inquiry; this circumstance may be subject to a heightened standard (e.g., reckless disregard or deliberate ignorance).
- experiences a significant increase in Medicare revenue and there is no apparent reason (e.g., a new partner is added to the practice or a new practice area is developed as an apparent reason); this circumstance may be subject to a heightened standard (e.g., reckless disregard or deliberate ignorance).
- learns or has knowledge of overpayments arising from Anti-Kickback or Stark Law violations.

All providers and suppliers receiving payments for Medicare or Medicaid should be alerted by counsel of the Final Rule. They should be hyper-aware of the ramifications for making any decisions on their own about what qualifies as "credible information," taking note that circumstances leading them to question whether something qualifies should induce them to seek legal counsel for each said circumstance because they are fact intensive. The guidance and references contained herein, therefore, may serve as a useful preliminary resource for that purpose and for initiating legal services to guide clients through the foregoing processes and standards established by DHHS.

Endnotes

1 Ms. Dornfeld is a Member of the law firm Brach Eichler L.L.C. Brach Eichler has offices in Palm Beach, Florida, Roseland, New Jersey

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and New York, New York. Ms. Dornfeld practices in Brach Eichler's prominent health law practice group, representing a broad array of health care providers in transactional and regulatory matters including, among many other areas, corporate and HIPAA compliance. Ms. Dornfeld has been a dedicated contributing author to the Florida Bar Health Law Section Newsletter, including *Anatomy of a HIPAA Breach: Counseling Your Client Through the Investigative and Reporting Process* and *Avoid Legal Pitfalls and Sham Transactions in Medical Directorships and Physician Arrangements*, published in 2015.

2 Section 1128J (d)(4)(C) defines "person" as a provider of services, supplier, Medicaid managed care organization ("MCO" defined in section 1903(m)(1)(A) of the Act), Medicare Advantage (MA) organization (defined in section 1859(a)(1) of the Act), or prescription drug plan (PDP) sponsor (defined in section 1860D-41(a)(13) of the Act).

3 "Overpayment" is defined by Section 1128J(d)(4)(B) as any funds a person received or retains under title XVIII or XIX after reconciliation that said person is not entitled to retain. In other words, it is the difference between the amount paid and that which should have been paid. Sometimes, the overpayment may be the entire amount where the payment violates another active provision in another act, such as the Stark or Anti-Kickback laws.

4 The Department of Health and Human Services, Centers for Medicare & Medicaid Services noted in its Final Rule, published in the Federal Register on February 12, 2016, that section 1128J (d) of the Act does not require the Secretary to promulgate regulations pursuant thereto, so while the new regulations apply only to Medicare, the statute is effective for Medicaid overpayments as well. The rule is specific to Medicare Part A and Part B. The overpayment rule for Medicare Part C and Part D were published on May 23, 2014 (79 Fed. Reg. 29843 (May 23, 2014)). Thus, while the statute applies to Parts A-D and Medicaid, the regulations approach Parts A and B, Parts C and D, and Medicaid, respectively, slightly differently.

5 81 Fed. Reg. 7653 (Feb. 12, 2016).

6 "Obligation" under the new rule and statute also adopts its definition under the False Claims Act (31 U.S.C. § 3729(b)(3)). It "means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from a statute or regulation, or from the retention of any overpayment."

7 31 U.S.C. § 3729(b) (also stating "knowing" or "knowingly" do not require proof of specific intent to defraud.

8 The preamble to the rule included examples of overpayment situations. Take note that the list is *not* exhaustive.

9 *See*, 81 Fed. Reg. 7653, 7656 (Feb. 12, 2016).

10 *Id.* at 7661.

11 *Id.* at 7662.

12 *Id.* at 7653.

13 *Id.* at 7653.

14 *Id.* at 7662.

15 81 Fed. Reg. 7653 7662 (Feb. 12, 2016).

16 *Id.* at 7665.

17 *Id.* at 7659.

Preemption Prevails: Amendment 7 and the Patient Safety and Quality Improvement Act

By David Hughes and Jamie Klapholz[1]

Introduction

In *Southern Baptist Hospital of Florida, Inc. v. Charles*,[2] the First District Court of Appeal found that Article X, section 25 of the Florida Constitution was expressly and impliedly preempted by the Patient Safety and Quality Improvement Act of 2005 ("PSQIA").[3] This decision has been appealed to the Florida Supreme Court, where it remains pending as of this writing.[4] If affirmed, *Charles* will have a significant impact on the culture of safety that the PSQIA seeks to promote, and deprive medical malpractice plaintiffs of an "important discovery tool"[5] that has been the subject of much debate since 2004.

The following article will outline the developments that gave rise to *Charles*, and briefly summarize a decision of great interest to hospitals, risk management departments, licensed healthcare professionals, and medical malpractice litigators in Florida and beyond.

II. Background: Amendment 7 and PSQIA

A. Amendment 7

Article X, section 25, of the Florida Constitution ("Amendment 7"), was approved by Florida voters on November 2, 2004.[6] Known as the "Patients' Right-to-Know About Adverse Medical Incidents," Amendment 7 provides patients with "a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident."[7]

As one commentator noted, Amendment 7 represented "one of the most sweeping changes in law and public policy ever adopted in Florida," and "[i]n one fell swoop . . . successfully breached the walls of privilege and immunity surrounding secret peer review, credentialing investigations, quality assurance, and risk assessments of both health care providers' and health care facilities' adverse medical incidents . . . ."[8] In the litigation arena, Amendment 7 has become an "important discovery tool for medical malpractice plaintiffs" because it provides litigants with broad access to previously privileged information about adverse medical incidents. Since its passage, Amendment 7 has engendered considerable ongoing debate, and withstood a number of state-law-based attacks, including the seminal 2008 case *Florida Hospital Waterman, Inc. v. Buster*.[9]

In addition to various state-law-based attacks, opponents have challenged Amendment 7 by invoking "federal preemption by statutes that require the confidentiality of certain records" such as the Health Care Quality Improvement Act ("HCQIA"), and the federal Contracts Clause.[10] In 2009, however, Florida's First and Fourth District Courts of Appeal concluded that neither the HCQIA nor the federal Contracts Clause preempted Amendment 7.[11]

B. Patient Safety Quality and Improvement Act and Statutory Privileges

In 2005, Congress passed the PSQIA to improve patient safety in the healthcare industry.[12] The PSQIA was passed after a 1999 Institute of Medicine (IOM) report entitled *To Err is Human: Building a Safer Health System* estimated that "at least 44,000 people and potentially as many as 98,000 people die in United States hospitals each year as a result of preventable medical errors."[13] In response, the IOM recommended that Congress pass legislation "to foster the development of a reporting system through which medical errors could be identified, analyzed, and utilized to prevent further medical errors."[14] The goal of this reporting program would be to facilitate an "environment in which health care providers are able to discuss errors openly and learn from them," and replace a "culture of blame" with a "culture of safety" that emphasized open communication and cooperation.[15]

Practically, the PSQIA created a "voluntary, confidential, non-punitive system of data sharing of healthcare errors for the purpose of improving the quality of medical care and patient safety."[16] The PSQIA would permit participating health care providers to create internal "patient safety evaluation systems" ("PSES") for the collection, management, and analysis of patient safety event data that could voluntarily be forwarded to a "patient safety organization" ("PSO").[17] Once data was in a PSO, it would be further collected and analyzed, and recommendations and feedback would be given to healthcare providers on ways to improve patient safety and quality of care.[18]

To incentivize provider participation, Congress created a "protected legal environment . . . [where] providers would be comfortable sharing data both within and across state lines," and "without the threat of information being used against [them]."[19] This included strict privilege and confidentiality protections for shared information, which the PSQIA termed "patient safety work product" ("PSWP"). Such protections were considered to be "the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events."[20]

III. Preemption: The Intersection of Amendment 7 and PSQIA

A. Charles: A Procedural History

In *Charles*, the First District Court of Appeal addressed the "intersection" of Amendment 7 and the PSQIA in the context of a medical malpractice case between members of the Charles family and Southern Baptist Hospital of Florida ("SBHF").[21] In the underlying litigation, plaintiffs filed three requests for production pursuant to Amendment 7, wherein they requested documents from SBHF that were: "(1) related to adverse medical incidents and (2) either related to any physician who worked for SBHF or arose from care and treatment rendered by SBHF during the three-year period preceding [plaintiff's] care and treatment and through the date of the third request."[22]

SBHF produced several responsive documents,[23] but argued that other potentially responsive documents were shielded from discovery pursuant to the privilege and confidentiality clauses in the PSQIA.[24] Thereafter, plaintiffs moved the trial court to compel production of these documents, and argued that the PSQIA "only protects documents created *solely* for the purpose of submission to a PSO and that information does not constitute PSWP if it was collected or maintained for another purpose or for *dual purposes* or if the information is 'in any way related' to a healthcare provider's obligation to comply with federal, state, or local laws or accrediting or licensing requirements."[25]

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Advising Buyers of Substance Abuse Businesses: Beware!

By Heather Miller[1]

Whether you work in healthcare or are a patient in the community at large, almost everyone who has received medical care has heard of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), one of the first comprehensive pieces of federal legislation to address the use and disclose of protected health information held by medical providers, health plans, and other "covered entities."[2] Far fewer are familiar with the more restrictive federal and Florida laws that provide privacy protection to alcohol and drug abuse patients.[3] The technical details of these regulations are not only important for providers and patients, but for private equity and other investors looking to purchase such businesses and reap the benefits of a lucrative business model.

Over the past few months there have been scores of articles written about the Substance Abuse and Mental Health Services Administration ("SAMHSA") proposed rules to modernize the Confidentiality of Alcohol and Drug Abuse Patient Records regulations, 42 C.F.R. Part 2 (commonly referred to as "Part 2"), which govern the disclosure of confidential patient information for federally assisted drug and alcohol treatment programs.[4] For-profit programs and private practitioners who use a controlled substance for detoxification or maintenance treatment of a substance use disorder are also subject to these regulations because such use requires a federal Drug Enforcement Administration ("DEA") registration and subjects the program and private practitioner to DEA regulations as a condition of DEA licensure. Part 2 was enacted, in part, as some patients avoid treatment for fear that public disclosure of their treatment will foster stigma and discrimination toward them. Part 2 provides substance abuse treatment patients with privacy protection by only allowing the disclosure of their treatment records, under limited circumstances, without their written consent. The Florida equivalent of Part 2 is Section 397.501, Florida Statutes, which in certain instances, is even more restrictive than Part 2. While the privacy and disclosure regulations are paramount to patients feeling secure in seeking treatment, they are an enormous obstacle for mergers and acquisitions involving substance abuse treatment businesses.

The heightened interest in the substance abuse market by investors came shortly after laws were passed giving treatment for mental health disorders payment parity with physical disorders.[5] Since potential investors may not necessarily be experts in the mental health industry, and some sellers may not be sophisticated health care systems, they are unaware of the laws that limit the disclosure of such substance abuse information. As a result of the restrictive nature of these laws, investors will not be able to freely conduct due diligence.

Many substance abuse providers are under the mistaken assumption that if they satisfy the requirements of HIPAA that they can disclose protected health information concerning a patient receiving treatment for a substance abuse disorder. However, the parameters under which patient treatment information can be disclosed under Part 2 and Section 397.501, Florida Statutes are far more restrictive.

De-identifying patient information is one way to avoid these restrictions, but many treatment providers do not de-identify their patient data in the billing and collection process. De-identifying such information during the sale process can not only be costly and cause delays, but there are also restrictions on the seller being able to retain a third party to de-identify such information. Therefore, a buyer will not be able to conduct a comprehensive financial due diligence and prepare its own audited financials because it will not be able to review all of the billing and collection records without potentially violating federal and Florida law. Instead, it will have to rely on financial data prepared by a business associate of the seller, who will have to perform its analysis onsite. De-identified patient records are not to be removed from the facility, copied or downloaded.

It is positive news that on February 9, 2016, the U.S. Department of Health and Human Services issued proposed rules that are aimed at modifying Part 2 with respect to sharing patient information to align with advances in the national health care delivery system. It is a sign that the government understands that laws need to adapt to changes in technology and health care delivery models. However, the regulators have failed to account for the surge in nationwide mergers and acquisitions of federally assisted and non-federally assisted treatment providers. The landscape in the substance abuse area is robust, but the laws, as they are currently structured, stifle corporate transactions. Unfortunately, the laws are not vague or forgiving. Therefore, counsel that are advising providers, need to be mindful of the restrictions against the disclosure of such protected health information in connection with a sale, merger or consolidation.

Endnotes

1 Heather S. Miller is senior counsel and member of the Health Law Practice Group in Broad and Cassel's Miami and Boca Raton offices. Here, she acts as general and special counsel to both hospitals and large medical groups. She centers her practice on complex health care transactions on behalf of physicians and hospitals, regarding regulatory compliance and federal and state fraud and abuse issues. Miller's devotion to and experience in health law has earned her multiple local and national acknowledgments in the South Florida Legal Guide and by the Cystic Fibrosis Foundation, where she was praised a "Top Up & Comer" from 2013 to 2016 and among the "40 under 40 Outstanding Lawyers in South Florida" in 2014.

2 Pub. L. 104-191, 110 Stat. 1936 (Aug. 21, 1996).

3 42 C.F.R., Pt. 2; Fla. Stat. § 397.501.

4 81 Fed. Reg. 6987 (Feb. 9, 2016).

5 *See, e.g.*, Mental Health Parity and Addiction Equity Act of 2008 (29 U.S.C. § 1185a).

Healthcare Providers, Listen Up: Accommodating Patients Who Are Deaf, Hard of Hearing or of Limited English Proficiency

By Karen M. Buesing and Steven A. Grigas[1]

Hospitals and health care providers who fail to provide appropriate auxiliary aids and services to patients and companions who are deaf or hard of hearing, are HIV positive or are not proficient in the English language continue to be the target of government enforcement actions. Hospitals and health care providers are well advised to review existing operations for compliance in this area and supplement or adjust as needed.

Recent Enforcement Actions

The nationwide Barrier-Free Health Care Initiative, a partnership between the Department of Justice Office of Civil Rights ("DOJ) and more than 40 U.S. Attorney's offices across the country, focuses enforcement efforts on ensuring that persons with disabilities have equal access to medical services and facilities. Since January 2015 alone, the DOJ has announced 10 public settlements with healthcare providers including hospitals, physician practices, a mental health treatment center, a skilled nursing facility and a mobile dental clinic. These and other settlements often arose out of patient or companion complaints that healthcare providers denied the patients' requests for American Sign Language interpreters during treatment, or refused them services because they were HIV-positive. A sampling of the allegations giving rise to these settlements include:

- A deaf patient who presented to the Emergency Care Center after falling from a ladder. He alleged that on multiple occasions during his six-hour visit, he requested a sign language interpreter but was not provided one, either in-person or by Video Remote Interpreter ("VRI".) The patient relied on his deaf friend to read lips and then sign to the patient, but he did not understand most of what was being communicated. The patient was discharged with instructions and medication, but said he did not fully understand the discharge instructions.[2]
- A female patient alleged that multi-location physician practice refused to schedule an elective tubal ligation surgery based on her HIV status. [3]
- A patient admitted to a hospital with suicidal thoughts repeatedly requested a sign language interpreter during her 13-day stay so that she could participate in group therapy and one-on-one therapy sessions. The hospital staff insisted she could hear and denied her request. Further, hearing patients had unlimited access to a public telephone that the complainant could not use because she was deaf. [4]
- The deaf father of a minor child alleged that a physician practice failed to provide a sign language interpreter and thereby denied him the equal opportunity to participate in the medical care of his child.[5]
- The deaf daughter and granddaughter of an 83- year-old, who was admitted at a skilled nursing facility for seven weeks of physical rehabilitation, were denied sign language interpreters effectively preventing them from communicating with the staff about her condition. They argued they were entitled to an interpreter, even though the patient's sister - who was not hearing impaired – arranged for the patient's admission, was identified as her financial conservator and was listed in admission records as her "responsible party." [6]
- The Office Manager of a mobile dental clinic informed an HIV-positive patient that the clinic could not perform a tooth extraction due to his HIV status and referred him to an AIDS clinic. Later that same day the General Manager of the clinic called and apologized and arranged for service the next day, which was performed without incident.[7]

The DOJ also has published multiple additional settlements of disputes between health care providers and persons of Limited English Proficiency ("LEP"). Many of these concerned effective communications and access to services and facilities.[8]

Legal Obligations of Health Care Providers

Several statutes apply to the legal obligations of health care providers for persons with communication related disabilities. Primarily, such obligations arise under the Americans with Disabilities Act 42 U.S.C. § 12181 *et seq*. ("ADA") and Section 504 of the Rehabilitation Act 29 U.S.C. § 794 ("Section 504"). The legal obligations for LEP persons arise under Title VI of the Civil Rights Act ("Title VI"). [9]

The ADA requires access to medical care services and the facilities where the services are provided. Private hospitals or medical offices are covered by Title III of the ADA as places of public accommodation.[10] Public hospitals and clinics and medical offices operated by state and local governments are covered by Title II of the ADA as programs of the public entities.[11]

Section 504 provides in part that no otherwise qualified individual with a disability can, by reason of her or his disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any executive agency.[12] Section 504 applies to service availability, accessibility, delivery, employment, and the administrative activities and responsibilities of organizations receiving federal financial assistance (including Medicare and Medicaid.)[13]

In addition to not discriminating against persons with disabilities, recipients of Federal financial assistance must ensure that their programs and activities provided in English are accessible to LEP persons and thus do not discriminate on the basis of national origin in violation of the prohibition against national origin discrimination in Title VI of the Civil Rights Act.[14]

Together, these laws require health care providers to ensure that their communications with people with disabilities or lacking English proficiency are as effective as their communications with people without disabilities. Health care providers must provide auxiliary aids and services, unless doing so would cause an undue burden to the facility or fundamentally alter the service being provided, and

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they must be provided free of charge.

When the Department of Justice Comes Knocking

Providers who fail to understand and meet their obligations under the ADA and Section 504 may find the DOJ Office of Civil Rights knocking on their doors. Typically, a patient or companion will complain, and the DOJ will initiate an investigation. The DOJ investigators will ask for the name and contact information of the provider's "Section 504 Coordinator." They will request copies of all written policies concerning communicating with patients and companions with disabilities, copies of all training materials, copies of all notices which inform patients of their rights to auxiliary aids and of how to file a grievance. They will ask the provider to identify its processes for the initial and ongoing assessments of communications needs, patient preferences and documentation of when and with whom the provider has used auxiliary aids and services. They will also typically interview the staff who directly served the patient and ask them about their Section 504 training, who their Section 504 coordinator is, what auxiliary aids and services are available, where the instructions for operating any auxiliary equipment (such as Video Remote Interpreting services) are maintained, and what information they convey to patients who want to file complaints.

Remedies for Violations

The DOJ will often ask a provider to enter into a public settlement agreement when violations are found.. Most settlement agreements require that providers commit to: providing appropriate auxiliary aids and services (unless it would result in an undue burden or fundamental alteration of the service); developing comprehensive Section 504 / ADA plans, procedures and training for dealing with persons with disabilities; and submit to three or more years of OCR oversight. Some also require the payment of a monetary penalty.

Complainants do not have to go to the government first; they can sue directly for relief. Under Title III of the ADA, private parties can sue for injunctions to stop discrimination and recover reasonable attorneys' fees, but not damages. They can also file complaints with the Attorney General, who can obtain not only injunctive relief, but also monetary damages, civil penalties of up to $50,000 for a first violation or $100,000 for any subsequent violation. Under Section 504 and Title VI of the Civil Rights Act, a private party who proves intentional discrimination can recover directly for both compensatory damages and injunctive relief, and as well as reasonable attorneys' fees. Notably, doctors or others who have the authority to address discrimination and institute corrective measures and who have knowledge of it but fail to adequately respond can be held individually liable.[15]

Understanding Providers' Obligations

Health care providers should have comprehensive polices and a Section 504 / ADA plan in place to deal with persons with disabilities or Limited English Proficiency. They should further ensure that personnel are properly trained to address their needs, or that other acceptable options are made available. Providers need not always provide an in-person interpreter; if Video Remote Interpreting provides effective communication for persons with disabilities, it can be sufficient to comply with the law. In February 2016, a Florida hospital obtained summary judgment in its favor in a case challenging the sufficiency of the use of VRI services in *Sunderland v. Bethesda Health, Inc.*[16]

It should be noted, however, that the National Association of the Deaf ("NAD") advocates against the use of VRI in the medical setting and "strongly believes that VRI services should be provided only if on-site interpreter services are unavailable." [17] Indeed, the NAD has sued District Hospital Partners in Washington, D.C. asserting that the hospital's VRI policy, although expressly permitted by ADA regulations[18], does not meet the regulations' mandate to provide effective communication in all circumstances.[19] The outcome of that lawsuit may further impact health care providers' obligations. In the meantime, health care providers need to understand their obligations, develop a compliance plan and train doctors and staff on dealing with patients and companions with communications disabilities.

Endnotes

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2 *Grady Memorial Hospital*, Atlanta, GA, January 12, 2016 Agreement at ¶4, available at http://www.ada.gov/grady_sa.html.

3 *North Florida Obstetrical & Gynecological Associates, P.A.*, Jacksonville, FL., January 7, 2016 Agreement ¶2, available at http://www.ada.gov/north_florida_sa.html.

4 *DeKalb Regional Crisis Center,* Decatur, GA, August 11, 2015 Agreement at ¶4, available at http://www.ada.gov/dekalb_crisis_ctr_sa.html.

5 *Srinivas Mukkamala, M.D., P.L.C*, Flint, MI., July 14, 2015 Agreement ¶2, available at http://www.ada.gov/mukkamala_sa.html.

6 *Fairfax Nursing Center,* Fairfax County, VA., July 6, 2015 Agreement at ¶¶ 3, 4, available at http://www.ada.gov/fairfax_nursing_ctr_sa.html.

7 *Dentexl Dental Mobile, Inc.*, Huntington Valley, PA., March 13, 2015 Agreement at ¶11 http://www.ada.gov/dentex_sa.htm.

8 http://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/limited-english-proficiency/index.html.

9 42 U.S.C. § 2000d.

10 42 U.S. C. §§12181-12189.

11 42 U.S.C. §§ 12131-12165.

12 29 U.S.C. § 794.

13 Federal financial assistance includes monetary and in kind types of assistance including grants, loans, sales/leases or permission to use federal property below market value, training, etc. In health care, Federal financial assistance encompasses federal funding like Medicare, Medicaid**,** NIH grants, and CDC monies. It does not encompass contracts of guarantee or insurance. 45 C.F.R. § 80.13(f).

14 42 U.S.C. § 2000d.

15 *Liese v. Indian River Cnty. Hosp. Dist.*, 701 F. 3d 334 (11th Cir. 2012) (determining that it was a factual question whether the actions of a hospital's doctors "may be attributed to the [h]ospital for purposes of establishing liability under the Rehabilitation Act" and remanding for a jury trial on that issue. On remand, the jury returned a verdict in favor of the hospital and the district court entered final judgment for the hospital. *Liese v. Indian River County Hosp. Dist., Case No. 2:09-cv-14388 (S.D. Fla. May 28, 2013).*

16 2016 BL 30243 (S.D. Fla. No. 13-80685, Feb. 3, 2016).

17 https://nad.org/issues/technology/vri; *see also* NAID's position statement on VRI available at https://nad.org/issues/technology/vri/position-statement-hospitals.

18 28 C.F.R. § 36.303(b)(1).

19 *Nat'l Ass'n of the Deaf v. Dist. Hosp. Partners,* LP (D.D.C. No. 1:14-cv-1122, 2/4/16); 2016 BL 31238.

Hospital Acquisitions of Physician Practices

By Marcy Hahn-Saperstein[1]

Increasing expenses, lowering reimbursements, and efforts to reign in health care costs are all drivers in encouraging synergy between hospitals and physicians. In an effort to find ways to jointly and efficiently deliver care, hospital acquisitions of physician practices has become quite commonplace. This article outlines the steps involved in structuring such an acquisition and identifies issues that typically arise in the "onboarding" process.

Due Diligence

Once a physician practice has been identified as a potential acquisition target, hospitals typically provide the practice with a data request to obtain highly detailed information about the operation of the practice. Physician practices concerned about delivering such highly confidential information to the hospital should request that the hospital execute a Nondisclosure Agreement prior to submitting information responsive to the data request. The information provided enables the hospital to conduct initial due diligence, evaluate the business of the practice, confirm that the hospital is interested in making an offer to acquire the practice and determine appropriate business terms for any potential offer. In addition, a thorough due diligence process can uncover some potential issues that may arise in the onboarding process.

Existing Noncompetes. Before engaging in any discussions with a physician for a potential acquisition, it is important to be sure that the physician is not subject to a noncompete agreement that may preclude his or her employment by the acquiring hospital.

Existing Space and Equipment. Reviewing the practice's real estate leases, equipment leases and any loans secured by equipment will uncover any issues that may require resolution prior to the execution of the practice acquisition documents.

Existing EMR System. Understanding the practice's medical records system enables a hospital to develop a strategy for the onboarding process. It is not always practicable for a physician to immediately utilize a hospital's electronic medical records system ("EMR") due to the training involved and the anticipated inefficiencies that occur in a physician practice when transitioning to a new EMR program. Identifying these issues early on avoids headaches in the onboarding process.

Existing Insurance Coverage. The hospital must understand the physician's insurance coverage and how the transition to hospital coverage will be handled, making sure that no gaps in coverage exist. Therefore, consideration must be given to the nature of the policy, whether it is claims-made or occurrence-based, and whether "tail" or "nose" coverage is necessary.

Qualitative Review. At the same time that the hospital is reviewing the documentation provided in response to the data request, the hospital should be engaging in a qualitative review of the practice, identifying some of the less tangible ways a new physician practice can improve the hospital's business. Similarly, the hospital should identify ways in which the hospital can improve on the management of the physician's practice through, for example, improved collection efforts, improved reimbursement rates, economies of scale, and centralized staffing that could be mutually beneficial. The hospital should also identify early if there are particular areas of training necessary from which the physician could benefit, such as on good coding practices, EMR, or hospital policies and procedures.

The hospital should also be vigilant of any red flags. Is the physician someone who can work cooperatively with the existing medical staff, hospital's nurses and other employees or can the physician be divisive and difficult? Has the physician's practice seen a lot of turnover by employed physicians or staff suggesting problems in the working environment? Does the physician have a troublesome malpractice history? Does the coding review reflect significant upcoding? Will the acquisition lead to defections by other members of the medical staff? Is the physician simply looking for a transition to retirement?

Letter of Intent/Nonbinding Term Sheet

Once the hospital has concluded that it wishes to proceed with an offer, hospitals will typically provide the details in a nonbinding "term sheet" or "letter of intent." That term sheet or letter of intent should be nonbinding with regard to all the business terms but should be binding with regard to certain provisions.

Binding Provisions typically include: (i) the confidentiality of the proposed terms; (ii) a no-shop clause that precludes the practice from considering transactions with other hospitals or entities for a period while negotiating definitive agreements with the offering hospital; (iii) a nonsolicitation provision precluding either of the parties from soliciting the employees of the other; and (iv) an authorization by all the physician owners of the practice entity that the physician with whom the hospital is dealing, is authorized to negotiate the documents on their behalf and to provide information on their behalf as requested, and that information provided to such physician will be deemed to have been provided to each of the physician owners. Each of the physician owners should be a signatory to the letter of intent or nonbinding term sheet.

Nonbinding Provisions typically include the key business terms in the operative documents that are addressed below.

Standard Documents

Asset Purchase. If a hospital plans to take over the space and equipment of a physician practice, then the hospital typically acquires the assets rather than the equity of a physician practice for various reasons. Most physician practices are organized as professional service entities that cannot be owned by hospitals. Hospitals prefer the lower risk involved in an asset purchase versus an equity purchase.

Asset List. One of the most important aspects of the asset purchase agreement is a complete understanding of which assets will be acquired and which will be excluded. The parties should inventory every item that the hospital expects to acquire and that the physician practice and its physicians understand they are selling. This inventory is useful in obtaining a fair market value appraisal of the assets and in aligning both parties' understanding of what is included in the acquisition.

Purchase Price. A crucial part of the asset purchase agreement is the determination of the purchase price. No amount of good lawyering and tight contracting will make up for the failure to pay a purchase price that complies with state and federal self-referral and anti-kickback statutes.[2]

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In general, the price must be fair market value, not determined in a manner that takes into account the volume or value of any referrals by the referring physician or other business generated between the parties and must be commercially reasonable even if the physician made no referrals.

Representations and Warranties. The asset purchase agreement typically includes various representations and warranties by the selling practice entity that, among other things, help identify any potential issues that were not caught during the due diligence phase and that may require resolution prior to closing the acquisition. For example, it must represent that it owns good and marketable title to all the assets, free and clear of all liens, leases or other encumbrances. A practice would not be able to make that representation with regard to a piece of expensive medical equipment that is subject to a security interest granted as part of a loan used to acquire the equipment. This is one of those issues that should have been identified during the due diligence process where the hospital requested information on debts related to equipment. The hospital needs to investigate how to handle the outstanding loan and the transfer of that piece of equipment.

Similarly, the practice entity typically represents that a listing of all contracts to which it is a party or to which the assets are subject is attached to the agreement and that they are all valid with no existing default. The hospital must determine whether it needs to assume these contracts for the proper continued conduct of the practice, as would be the case with an important piece of medical equipment that is leased, for example.

The practice entity usually also makes representations about employee matters, listing benefit plans, perquisites and all basic information about employees, as listed earlier in the due diligence portion discussed above. The hospital will need to make determinations about which employees, physicians, physician extenders and staff will be offered employment.

The practice entity also makes representations regarding existing or threatened litigation or investigations, reviews or other proceedings against it or any of its physicians or other patient care employees. The hospital needs to understand all potential liabilities, especially, for example, if there are pending malpractice cases, licensure challenges or Medicare or Medicaid audits or potential recoupments of overpayments.

The practice entity also makes representations regarding the existence of all permits, certifications, or authorizations by any governmental authority necessary for the operation of its business. For example, an orthopedic practice may have an x-ray machine that must be registered with the state's radiation control authority. A determination must be made whether that registration can be transferred or whether a change of ownership or new registration application must be filed after the acquisition.

Indemnification. A key provision to include in the asset purchase agreement pertains to indemnification. If a hospital discovers a misrepresentation by the physician practice entity, it may seek indemnification of any resulting claims or losses from the physician practice entity or, if guaranteed by the physician owners, from the physician owners themselves. Personal guarantees by the physician owners is an important aspect of this indemnification obligation. Following the sale of assets of a physician practice, the practice entity will likely only remain in existence to collect its outstanding receivables. For that reason, the entity will have few assets to pursue in the event the hospital seeks legal redress for any breach of its indemnification obligation and the hospital should preserve its ability to collect for these losses by securing a guaranty of the obligations by the physician owners. A tight indemnification provision may be useless without obtaining personal guarantees of the practice entity's obligations under the asset purchase agreement.

Space Lease. The hospital should have determined during the due diligence process, whether the physician will remain in the office in which the physician practiced before, thereby requiring a determination of how the hospital will assume control of that space. If the hospital must obtain landlord consent in order to assume the lease, or if the hospital wishes to renegotiate a longer term lease, that process likely requires significant lead time. If the landlord of the office space is an entity owned or controlled by the physician, that lease must also comply with state and federal self-referral and anti-kickback statutes. Leasing an

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appropriate amount of space and paying fair market value for that space will be key considerations in that analysis. In addition to provisions typically included in a commercial lease, the parties should consider whether to include an early termination of the lease in the event of the termination of the physician's employment agreement.

Employment Agreement.

Nature of the Services. The employment agreement should identify the nature of the physician's role and the amount of effort expected. Will the physician be providing only professional clinical services or is he or she expected to perform any administrative functions? What are their specific duties? Are they expected to participate in particular hospital committees? Are they full time or part time and what is the expected minimum hourly requirement? What is their on-call obligation? Will they have a title? To whom will they report? How will their evaluation be handled? In which locations will the physician provide services? There are many aspects of the physician's specific duties that must be clearly outlined to avoid surprises.

Representations and Qualifications. Usually, the physician represents that he or she is in good standing to practice medicine in the state, holds state and federal registrations to prescribe medication and is a provider in good standing with the Medicare and Medicaid programs. It may also be appropriate for the physician to represent that the physician is board certified in a specific specialty. It is important that the physician covenant that those representations will remain true throughout the term of the agreement and to notify the hospital promptly upon discovering that any of those representations are no longer true.

Compensation. The compensation is, of course, a key component of the agreement and must comply with state and federal self-referral and anti-kickback statutes. Of paramount importance is the payment of fair market value compensation. This compensation may take many forms. It may be entirely a guaranteed salary, a formula based entirely on productivity or a guaranteed base component coupled with an incentive component. When compensation contains an incentive component, it may be based upon quality metrics, productivity metrics or a combination of the two.

Productivity, itself, may have different metrics. For example, it may be based upon collections, which puts the physician at risk of poor collections, or based on work relative value units, which puts the hospital at risk of poor collections.

Regardless of the method of calculating compensation, to comply with state and federal self-referral and anti-kickback statutes, compensation may only be based upon the physician's own productivity or that of physician extenders under the physician's direct supervision. In general the compensation may not take into account the volume or value of referrals to other areas of the hospital. The compensation must be consistent with the fair market value of the services and be commercially reasonable even if no referrals were made to the employer.

Benefits and Perqs. The physician's compensation includes the package of benefits and perquisites offered by the hospital. Such benefits and perquisites must be considered as part of any fair market value analysis.

Restrictive Covenants. Restrictive covenants are another key component of these agreements. These usually include three different types: (i) Confidentiality; (ii) Nonsolicitation; and (iii) Noncompetes.

The confidentiality requirement should extend to the terms of the agreement and all of the hospital's practices, procedures, payor contracts, marketing strategies, and other business information. The nonsolicitation requirement precludes the physician from soliciting the hospital's employees, patients, and vendors to terminate their respective relationships with the hospital.

With regard to the noncompete provision, a restrictive covenant may restrict a physician from competing within a defined area for some period of time following the termination of the physician's employment. The enforceability of these provisions varies by state and what is deemed reasonable in one may be unreasonable in another. Similarly, several miles may be a reasonable distance in a suburban area within a state, but may be unreasonable in a highly urban area in that same state.

While a buyer of a practice naturally wants to protect the asset it acquired, some of the business considerations may be different in the context of a hospital acquisition of a physician practice. First, the hospital cannot interfere with the physician-patient relationship. Rather, it can simply make that physician less convenient for a patient to visit because the physician is precluded from practicing within a certain restricted area. Second, a hospital may prefer to have that physician continue on its medical staff and practice within the community, rather than leave the community and, perhaps, take the physician's patients with him or her. Accordingly, hospitals may choose to allow physicians who sell their practices to return to the private practice of medicine as they were practicing prior to the acquisition and limit the imposition of a restrictive covenant only to those situations where a physician would be employed by, or otherwise affiliated with, a competing hospital.

Professional Malpractice Insurance. Another important provision in the employment agreement pertains to the provision of malpractice insurance. This is another area in which potential issues should have been flagged in the due diligence process. There are numerous logistical issues to resolve and the details of coverage should be clearly delineated in the employment agreement, such as the type and amount of coverage and who will pay for tail or nose coverage, if required.

Termination. Termination provisions are also important in employment agreements. Typically, hospitals reserve the right to immediately terminate the agreement in certain situations, such as upon the imposition of restrictions on the physician's license, DEA registration or suspension from the Medicare or Medicaid programs. These incidents are examples of issues that cannot be cured

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by the physician without first significantly hindering the physician's ability to practice or bill for his or her services. Certainly, in the case of a restriction on licensure, it may preclude a physician from practicing at all until such restriction is lifted.

Other breaches may give rise to an opportunity for the physician to cure the breach prior to termination. For example, if the physician fails to perform some duty, such as completion of medical records in a timely manner, the hospital may provide the employee with notice and an opportunity to cure. However, this process may not adequately address the status of the physician who habitually engages in that breach. A hospital may further clarify that if a physician receives one notice of a breach and cures, a second or perhaps third incident of the same breach will entitle the hospital to terminate the agreement without an opportunity to cure.

Onboarding Issues

After the transaction has closed, the work of integrating the physician practice begins. The key to a smooth integration is the early identification of potential issues during the due diligence process, as described above, thereby providing the parties time to resolve those issues in an efficient manner.

One other issue that exists in all physician practice acquisitions pertains to the credentialing of the physicians on Medicare, Medicaid and insurance payor panels. This process can take over 60 days for approval, creating a significant cash flow problem. Anticipating this problem can help minimize the disruption.

Conclusion

While this article outlines many potential issues and pitfalls in the process of acquiring a physician practice, careful due diligence, analysis, planning, and drafting can facilitate a positive experience for both parties.

Endnotes

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2 42 U.S.C. § 1320a-7b (federal Antikickback statute); Fla. Stat. § 456.054 (Florida's kickback statute).

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In three separate court orders, the trial court agreed with plaintiffs and reasoned that the requested information lost its PSQIA privilege because "it was collected or maintained for a purpose other than submission to a PSO or for '*dual purposes*.'"[26] In other words, since the records at issue were created for parallel federal (PSQIA) and state (Amendment 7) purposes, the trial court concluded that SBHF was not entitled to the foundational privilege and confidentiality clauses in 42 U.S.C. § 299b-21(7)(A)-(B).

B. The First DCA Finds that Amendment 7 Is Expressly and Impliedly Preempted by the PSQIA

On appeal,[27] the First District Court of Appeal's "starting point and guidepost" was the "clear and unambiguous" text of the PSQIA.[28] According to the First District Court of Appeal, the PSQIA "clearly and unambiguously" defined what was, and what was not, PSWP.[29] The Charles court also noted that the PSQIA made it very clear that the definition of PSWP "should not be construed to relieve a provider's duty to respond to federal, state, or local law obligations with information that is not privileged or confidential."[30]

After construing the provisions of 42 U.S.C. § 299b-21(7)(A)-(B) *in pari materia*, the *Charles* court concluded that the documents at issue "*clearly meet the definition of PSWP because they were placed into [SBHF's] PSE system where they remained pending submission to a PSO*."[31] The *Charles* court further reasoned that the documents at issue "also do not meet the Act's definition of what is not PSWP."[32]

In addition to its focus on the plain federal statutory text, the Charles court addressed plaintiffs' flawed "dual purpose" argument: i.e., the idea that because hospitals "may also be required under a state statute, rule, licensing provision, or accreditation requirement" to create adverse incident records, the documents' "PSWP status is removed, and the documents are stripped of any federal protection."[33]

The court again expressed fidelity to the PSQIA's plain text by noting that the dual purpose argument "incorrectly impose[d] additional items into the definition of PSWP" that do not appear in the PSQIA's plain text.[34] The court continued by noting that "[n]owhere does the definition state that a document may not simultaneously be PSWP and also meet a state reporting requirement."[35] Looking outside the plain text of the PSQIA, the court referenced the United States Department of Health and Human Services (HHS) rule guidance that "specifically addresss[ed]" such a dual purpose scenario, and "assur[ed] providers that they may place information into their PSE system with the expectation of protection and may later remove the information if the provider determines that it must be reported to the State."[36]

In direct terms, the *Charles* court remarked that plaintiffs' dual purpose argument gave "the false impression that federal protection under the Act and state compliance have to be mutually exclusive—they do not."[37] Instead, the court noted that the PSQIA actually gave providers the "flexibility" to collect and maintain information "in the manner it chooses with the caution that nothing should be construed to limit any reporting or recordkeeping requirements under state or federal law."[38] The fact that some documents "may also satisfy state reporting or recordkeeping requirements" like Amendment 7, according to the First District, is simply "not the relevant inquiry."[39]

After concluding that the documents at issue were protected by PSQIA's patient safety work product provisions, the court turned to the issues of express and implied preemption. [40] As to express preemption, the court remarked that the plain text of the PSQIA mandates that PSWP "shall be privileged" notwithstanding "any other provision of Federal, State or local law," and that PSWP is "not subject to disclosure during discovery in connection with a Federal, State, or local

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civil, criminal, or administrative proceeding, among other ways."[41] As to implied preemption, the court turned the dual purpose argument on its head by observing that "compliance with both federal and state law would be impossible."[42] After all, if otherwise federally privileged PSWP had to be produced in response to a formal Amendment 7 litigation request, production of such "categorically protected" materials would contravene the PSQIA.

Accordingly, the *Charles* court reversed the trial court's decision to compel the documents at issue, and found that SBHF was "entitled to the federal protection under the [PSQIA]."[43]

IV. Conclusion

It appears as though the Florida Supreme Court will have the final say on the intersection of Amendment 7 and the PSQIA. As of April 11, 2016, the Florida Supreme Court's online case docket indicates that the appellate process is moving forward, and that a number of interested entities have filed amicus briefs. For now, however, *Charles* is the law of the land, and hospitals, risk management departments, and licensed healthcare professionals can rest assured knowing that the sensitive and privileged documents housed in PSOs will not be subject to discovery pursuant to an Amendment 7 request.

Endnotes

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2 178 So. 3d 102 (Fla. 1st DCA 2015), appeal docketed, No. SC15-2180 (Fla. Nov. 25, 2015).

3 42 U.S.C. § 299b-21 *et seq*.

4 Florida Supreme Court Case Docket, No. SC15-2180, http://jweb.flcourts.org/pls/docket/ds_docket?p_caseyear=2015&p_casenumber=2180&psCourt=FSC&psSearchType= (last visited Apr. 11, 2016).

5 *Charles*, 178 So. 3d at 105.

6 J.B. Harris, *Riding the Red Rocket: Amendment 7 and the End to Discovery Immunity of Adverse Medical Incidents in the State of Florida*, Fla. Bar Journal, Mar. 2009, at 20. Amendment 7 was passed by more than 81% of Florida voters and was later incorporated into Article X, Section 25 of the Florida Constitution. Since its passage, it has commonly been referred to by courts and commentators as Amendment 7.

7 Art. X, § 25(a), Fla. Const. Amendment 7 broadly defines an "adverse medical incident" to include "any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient [.]" Art. X, § 25(c)(3), Fla. Const.

8 Harris, *supra* note vi, at 20.

9 984 So. 2d 478 (Fla. 2008).

10 Kelly G. Dunberg, Note, *Just What the Doctor Ordered? How the Patient Safety and Quality Improvement Act May Cure Florida's Patients' Right to Know About Adverse Medical Incidents (Amendment 7)*, 64 Fla. L. Rev. 513, 529-30 (2012).

11 *See Columbia Hosp. Corp. of S. Broward v. Fain*, 16 So. 3d 236, 241-44 (Fla. 4th DCA 2009); *W. Fla. Reg'l Med. Ctr. v. See*, 18 So. 3d 676, 684-88 (Fla. 1st DCA 2009).

12 Pub.L. No. 109–41, 119 Stat. 424, codified at 42 U.S.C. § 299b–21 *et seq.*

13 *Charles*, 178 So. 3d at 105.

14 *See* S.Rep. No. 108–196, at 3–4 (2003); H.R.Rep. No. 109–197, at 9 (2005).

15 H.R.Rep. No. 109–197, at 9 (2005). *See also* Patient Safety and Quality Improvement, 73 Fed. Reg. 8,112, 8,113 (proposed February 12, 2008); *See* S.Rep. No. 108–196, at 2 (2003); 73 Fed. Reg. at 70,749.

16 *Charles*, 178 So. 3d at 105.

17 42 U.S.C. § 299b–21(6).

18 *See* 42 U.S.C. § 299b–24; 73 Fed. Reg. at 70,733. The information reported to PSOs is also shared with a central clearing house, the Network of Patient Safety Databases, where the data is aggregated and made available to providers as an evidence-based management resource. See 42 U.S.C. § 299b–23.

19 *Charles*, 178 So. 3d at 105; 73 Fed. Reg. at 70,732.

20 73 Fed. Reg. at 70,741.

21 The underlying litigation in *Charles* was a:

medical malpractice action initiated by the respondents, Jean Charles, Jr., as next friend and duly appointed guardian of his sister, Marie Charles, and her minor children, Ervin Alston, Angel Alston, and Jazmin Houston (the respondents). The respondents claimed that Marie Charles suffered a catastrophic neurological injury due to Baptist's negligence.

Charles, 178 So. 3d at 106.

22 *Id.*

23 *Id.* The documents SBHF produced included Code 15 Reports required by section 395.0197(7), Florida Statutes, Annual Reports required by section 395.0197(6), Florida Statutes, and two occurrence reports specific to plaintiffs' child that were extracted from SBHF's "PSE system before they were reported the PSO." *Id.*

24 *Id.*

25 *Id.* at 106-07 (emphasis in original).

26 *Id.* at 107.

27 Before addressing the conflict *sub judice*, the First District concluded that SBHF had "made a sufficient showing of irreparable harm to invoke this Court's [certiorari] jurisdiction." *Id.* at 107.

28 *Id.* at 108.

29 *Id.* at 108. 42 U.S.C. § 299b–21(7)(A) defines patient safety work product thusly:

(A) In general

Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—

(i) which—

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities;

and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

42 U.S.C. § 299b–21(7)(B)(i)-(ii) also provides that the following is not protected PSWP:

(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

30 *Charles*, 178 So. 3d at 108. 42 U.S.C. § 299b–21(7)(B)(iii) notes the following with respect to federal, state, or local law reporting obligations:

(iii) Nothing in this part shall be construed to limit—

(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

31 *Charles*, 178 So. 3d at 108 (emphasis added).

32 *Id.*

33 *Id.* at 109.

34 *Id.*

35 *Id.*

36 *Id.* (citing 73 Fed. Reg. at 70,742).

37 *Id.*

38 *Id.*

39 *Id.* at 110 (citing Art. VI, cl. 2, U.S. Const.).

40 *Id.* at 110.

41 *Id.* at 110 (citing 42 U.S.C. § 299b–22).

42 *Id.* (citing *State v. Harden*, 938 So. 2d 480, 486 (Fla. 2006)).

43 *Id.*

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Payer Manual provide that Medicare has both contractual and statutory rights to recovery from primary payers.[12]

Whenever a primary payer exists, Medicare is treated as a secondary payer and is only responsible for paying any additional medical expenses when benefits under the primary plan have been exhausted. Specifically, 42 U.S.C. § 1395y(b)(2)(B)(i) states:

> [t]he Secretary may make payment under this subchapter with respect to any item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly. Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

Accordingly, Medicare may make conditional payments when the primary payer will not pay or did not pay promptly. However, when CMS or an MAO determines that payment by a primary plan could be made, reimbursement of the conditional payments made by Medicare is both proper and in accordance with Federal statute.[13] Within the context of private health insurance companies that provide Medicare Part C, this means that Federal law provides a method by which these companies can recoup unnecessarily-made expenditures on behalf of themselves as well as the Medicare program.

Medicare Part C authorizes, but does not compel, an MAO to charge a primary plan for medical expenses paid on behalf of a participant. Federal statutes explicitly address the ability of MAOs to assert claims for reimbursement or subrogation for benefits where they are secondary payers; Congress expressly provided that "[*n*]*otwithstan*ding any other provision of law," a secondary-payer MAO may charge the primary payer or the enrollee for benefits paid.[14]

C. Private Cause of Action

42 U.S.C. § 1395y(b)(3)(A) creates a private cause of action for any entity with standing[15] to sue a primary plan that fails to make the primary payment on behalf of a claimant. The statute further provides that if a private litigant is successful in its action, it may also recover double damages.[16] This not only provides an MAO with a legal remedy against a primary plan that failed to make statutorily-obligated payments, but also creates an "incentive for healthcare providers to bring lawsuits to vindicate Medicare's interests."[17] The nature of the MSPA demonstrates, rather convincingly, that Congress is highly motivated to bring down the cost of administering Medicare benefits.

D. Case Law

As MSP-related litigation is relatively new, most courts and practitioners focus on the following cases.

1. *Bio-Medical Applications of Tenn., Inc. v. Cent. States Southeast & Southwest Areas Health & Welfare Fund,* 656 F.3d 277 (6th Cir. 2011)

In *Bio-Medical,* an employer's group health plan denied coverage for dialysis treatment as the insured became Medicare-eligible after being diagnosed with end-stage renal disease. The insured assigned her rights under the insurance plan to Bio-Medical, the dialysis center at which she was receiving treatment, and Bio-Medical sued the group health plan provider for unpaid claims.

In finding that Bio-Medical was entitled to payment, the U.S. Court of Appeals for the Sixth Circuit rationalized that to do otherwise would be "forcing Medicare to bear the full burden by itself," making Medicare not only the secondary payer, but "the only payer."[18]

The Bio-Medical Court also upheld the MSPA's direct cause of action for private parties:

> double damages provide a needed incentive for private plaintiffs to bring claims against private insurers that have shifted costs to Medicare, so that Medicare is alerted and can seek reimbursement. Healthcare providers, not the Medicare bureaucracy, are presumably in the best position to observe when private insurers have refused to pay for an insured patient's treatment due to the patient's eligibility for Medicare.[19]

2. *In re Avandia Marketing,* 685 F.3d 353 (3d Cir. 2012)

The appellate court in Avandia took the logic used in Bio-Medical a step further finding that an MAO had a private cause of action under the MSPA. In Avandia, Humana Medical Plan sued GlaxoSmithKline for its refusal to consider Humana's Medicare treatment claims in the settlement proceedings related to the use of Avandia, a Type 2 diabetes drug.

In reversing the decision of the lower court, the U.S. Court of Appeals for the Third Circuit found that "the plain text of [the MSPA] sweeps broadly enough to include MAOs" and deference to CMS regulation required a finding that MAOs have the same right to recover as the Medicare Trust Fund does.[20]

The Court also looked to Congress' policy rationale behind the creation of the Medicare Advantage program in the construction of its holding. By harnessing the power of private sector competition, the Medicare Advantage program was meant to stimulate innovation that would ultimately create a more efficient and less expensive Medicare system.[21] Without the ability to pursue reimbursement for MSP claims, "MAOs would be at a competitive disadvantage, unable to exert the same pressure and thus forced to expend more resources collecting from such payers."[22]

3. *Humana Medical Plan, Inc. v. Reale,* 180 So.3d 195 (Fla. 3d DCA 2015)

In Florida, the ruling in *Humana Med. Plan, Inc. v. Reale* has created an even broader scope for MAOs seeking recovery under the MSPA in state courts. The *Reale* case concerned an action brought by an enrollee against an MAO, and held that an enrollee must seek to adjudicate a Medicare benefit dispute with its MAO through the plan's own administrative procedures and exclusively in federal court. However, although an enrollee must seek redress through administrative remedies, an MAO is not subject to the same requirements under federal law.[23]

In addressing the MSPA, the Third District followed Avandia and held that the MSPA "establishes a private cause of action for double damages when a primary plan does not provide reimbursement."[24]

> Under the Act, Medicare payments "may not be made" if "payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including self-insured plan) or under no fault insurance.[25]

E. Conclusion

Unlike other areas of the Medicare

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Act, the MSPA's private cause of action is rather straightforward. Although MSPA related litigation has started to heat up throughout the country, the MSPA private cause of action is here to stay.

Endnotes

1 The authors, John H. Ruiz and Frank C. Quesada, are attorneys with the MSP Recovery Law Firm. They specialize in health care litigation throughout Florida. The majority of their practice is focused on working with MSP Recovery, a health care data analytics company that identifies and pursues claims on behalf of HMOs, MSOs, IPAs and ACOs. Also contributing to this article were Diana Sun, Esq. and Andre Vazquez.

2 *Humana Medical Plan, Inc. v. Reale,* 180 So. 3d 195 (Fla. 3d DCA 2015) (quoting *Cooper Univ. Hosp. v. Sebelius*, 636 F.3d 44, 45 (3d Cir. 2010)).

3 *Mich. Spine & Brain Surgeons, PLLC v. State Farm Mut. Auto. Ins. Co.*, 758 F.3d 787, 790 (6th Cir. 2014).

4 *See* 42 U.S.C. § 1395y(b); *Fanning v. United States,* 346 F.3d 386, 388-89 (3d Cir. 2003).

5 *Id.* at § 1395y(b)(2)(A)(ii).

6 *Id.* at 42 U.S.C. § 1395y(b)(2)(A).

7 *Id.* at § 1395y(b)(2)(B)(i).

8 *Id.*

9 *Id.* § 1395w-22(a)(4).

10 *42 C.F.R.* § 422.108(d).

11 42 U.S.C. § 1395y(b)(2)(B)(ii).

12 42 C.F.R. § 411.22(b)(3); *MMA Amendments to the Medicare Secondary Payer (MSP) Provisions*, 71 Fed. Reg. 9466-9471, 9468 (Feb. 24, 2006); *Medicare Secondary Payer Manual,* (CMS Pub. 100-05) Chapter 2, §§ 40.2 and 60.1.

13 42 U.S.C. § 1395y(b)(2)(B)(ii).

14 42 U.S.C. § 1395w-22(a)(4).

15 CMS regulations have clarified that "any entity" includes beneficiaries, providers, suppliers, physicians, attorneys, state agencies, and private insurers. 42 C.F.R. § 411.24(g) (2014); *Joerg v. State Farm Mut. Auto. Ins. Co.*, 176 So. 3d 1247 (Fla. 2015). This includes: providers (*Mich. Spine & Brain Surgeons, PLLC v. State Farm Mut. Auto. Ins. Co.*, 758 F.3d 787 (6th Cir. 2014)); and beneficiaries (*Manning v. Utils. Mut. Ins. Co.*, 254 F.3d 387 (2d Cir. 2001); *Stalley v. Catholic Health Initiatives*, 509 F.3d 517 (8th Cir. 2007)).

16 *Id.*

17 *See Bio-Med. Applications of Tenn., Inc. v. Cent. States Se. & Sw. Areas Health & Welfare Fund*, 656 F.3d 277 (6th Cir. 2011).

18 *Id* at 283 (emphasis added).

19 *Id.* at 295.

20 *Id.* at 357.

21 *See Id.* at 363.

22 *Id.* at 364.

23 *Collins v. Wellcare Healthcare Plans, Inc.*, 73 F.Supp.3d 653 (E.D. La. 2014), which the *Reale* court relies on, held that "[the MAO's claim] is not subject to the same exhaustion requirement as [the enrollee] because 42 U.S.C. § 405(h) does not require Medicare organizations to exhaust administrative remedies." *Id.* at 662.

24 180 So. 3d at 198, n. 1.

25 *Id.* at 200.

Nomination Committee Report

Grigas nominated to chair Bar's Health Law Section

The Health Law Section's Nominating Committee has nominated the following officers for 2016-17: Steven Grigas for chair, Nicholas Romanello for chair-elect, Gregory Chaires for treasurer and J. Everett Wilson for secretary.

Charmaine Chiu will serve as the immediate past chair.

The committee nominated the following members to the executive council for the 2016-19 term: Radha Bachman, Allen Grossman, Patricia Huie, Shachi Mankodi, Jason Mehta, Christine Whitney, and Adam Maingot (First Alternate).

The Health Law Section will elect its officers and executive council members on June 16 during The Florida Bar's Annual Convention in Orlando, Florida. All members of the Health Law Section are encouraged to attend the meeting and section reception, which will immediately follow.

Section 7.4 of the section bylaws allows for other nominations to be made by petition of at least 15 voting members of the section. The petition must be filed with the chair no later than 30 days prior to the date of the Annual Convention. Petitions may be emailed to Chair Chiu at cchiu@smithhulsey.com.

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