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Phase Two of HIPAA Audit Program (Finally) Begins  
By: Dianne K. Pledgie, Esq., Feldesman Tucker Leifer Fidell LLP

After several delays, the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) announced on March 21st the next phase of audits to assess compliance with the HIPAA Privacy, Security and Breach Notification Rules. This article provides background on the HIPAA audit program, describes OCR’s plans for the Phase Two audits, and offers community behavioral health organizations (CBHOS) guidance to prepare for the Phase Two audits.

Background on the HIPAA Audit Program

The current HIPAA audit program was developed as the result of a mandate by the Health Information Technology for Economic and Clinical Health (HITECH) Act which was enacted as part of the American Recovery and Reinvestment Act of 2009. Prior to the audit authority established in HITECH, OCR’s enforcement was primarily carried out through the resolution of written complaints filed through its regional offices. After the passage of HITECH, and as it continued to investigate written complaints, OCR developed a pilot program to audit covered entities and business associates for compliance with HIPAA.

Between 2011 and 2012, the pilot program audited 115 covered entities in the following areas: breach notification; security (administrative safeguards, physical safeguards, technical safeguards); and privacy (Notice of Privacy Practices, right to request privacy protection of protected health information [PHI], access of individuals to PHI, administrative requirements, uses and disclosures of PHI, amendment of PHI, accounting of disclosures). Findings included:
- Two-thirds of entities lacked a complete and accurate security risk assessment
- 60% of the findings and observations related to the Security Rule
- 11% of the entities had no findings
- 59% of responding covered entities were not aware of the audit program prior to receiving notification that they were selected for participation.

Details on Phase Two Audits

A November 2013 report by the Office of Inspector General (OIG) for HHS found that OCR failed to conduct periodic audits of covered entities to ensure compliance with Security Rule requirements as required under the HITECH Act. The OIG’s report found that OCR continued to rely on a complaint-driven approach instead of a proactive compliance audit process and
recommended that OCR conduct periodic audits to ensure compliance with the Security Rule.

In 2014, OCR announced that it expected the Phase Two audits to begin during the summer of 2014 and last into 2016, that the audits would include both covered entities and business associates; and OCR would primarily conduct desk audits with auditees uploading documents via a web portal.

In 2015, the OIG issued two reports focused on the lack of HIPAA oversight by OCR. The OIG recommendations included that OCR fully implement a permanent audit program and maintain complete documentation of covered entity compliance with corrective actions plans in its program information management system. In response to the OIG reports, OCR announced that it expected to start the second phase of its HITECH-mandated audit program in 2016.

**Phase Two Audit Process Announced**

In mid-March, OCR announced that the Phase Two HIPAA audit program had commenced. Nearly all covered entities and business associates are eligible for audit, including covered individual and organizational providers of health services such as community behavioral health organizations; health plans of all sizes and functions; health care clearinghouses; and a range of business associates of these entities. OCR expects covered entities and business associates to provide the auditors their full cooperation and support during the audit process.

The OCR has announced the following steps for Phase Two of the HIPAA audit program:

1. *Develop the audit pool*

   OCR is currently developing a pool of potential auditees. OCR is identifying pools of covered entities and business associates that represent a wide range of health care providers, health plans, health care clearinghouses and business associates. Sampling criteria for auditee selection will include size of the entity, affiliation with other healthcare organizations, the type of entity and its relationship to individuals, whether an organization is public or private, geographic factors, and present enforcement activity with OCR. OCR will not audit entities with an open complaint investigation or that are currently undergoing a compliance review.

   OCR is sending emails to covered entities and business associates asking that they verify their contact information and/or provide the appropriate contact information. The emails are being sent from the following email address: [OSOCRAudit@hhs.gov](mailto:OSOCRAudit@hhs.gov).

   According to the sample notification provided by OCR, recipients have 14 days to respond to the initial email. Recipients must either: (1) confirm their identity and email address as
the primary contact OCR should use regarding the audit program or (2) provide updated primary and secondary contact information. If OCR does not receive a response, the letter states that they will use the email address for future communication with the entity. The letter goes on to state that “failure to respond will not shield your organization from selection.”

If a covered entity or business associate fails to respond to information requests, OCR will use publically available information about the entity to create its audit pool. An entity that does not respond to OCR may still be selected for an audit or subject to a compliance review.

2. Pre-audit screening

Once entity contact information is obtained, OCR will provide potential auditees in the audit pool with a questionnaire designed to gather data about the size, type, and operations. As a part of the pre-audit screening questionnaire, OCR will ask entities to identify their business associates.

3. Selecting covered entities and business associates to audit

OCR stated that it will select a random sample of entities from the audit pool. OCR will then notify the selected covered entities in writing through email about their selection for a desk audit. The notification letter from OCR will introduce the audit team, explain the audit process and discuss OCR’s expectations in more detail.

4. Conducting desk and onsite audits

OCR stated that both the desk and onsite audit process will employ common audit techniques. Details released about the audits include the following:

Desk audits: OCR will first conduct desk audits of covered entities followed by a second round of desk audits of business associates. These audits will examine compliance with specific requirements of the Privacy, Security, or Breach Notification Rules and auditees will be notified of the subject(s) of their audit.

Entities selected for a desk audit will be sent an email notification of their selection and will be asked to provide documents and other data in response to a document request letter. OCR expects covered entities that are the subject of an audit to submit the requested information via OCR’s secure portal within 10 business days of the date on the information request. Audited entities will submit documents on-line via a new secure audit portal on OCR’s website. All desk audits in this phase are scheduled to be completed by the end of December 2016.

On-site audits: The third set of audits will be onsite and will examine a broader scope of requirements from the HIPAA Rules than desk audits. Some desk auditees may be subject to a subsequent on-site audit.
To date, OCR has not provided details about what the on-site audits will examine except to state that they will be more comprehensive than the desk audits and cover a wider range of requirements from the HIPAA Rules.

Entities will be notified via email of their selection for an on-site audit. The auditors will schedule an entrance conference and provide more information about the on-site audit process and expectations for the audit. Each on-site audit will be conducted over three to five days on-site, depending on the size of the entity.

5. **Audit findings and reports**

**Desk audits:** After the documents are received from covered entities, the auditor will review the information submitted and provide the auditee with draft findings. Auditees will have 10 business days to review and return any written comments to the auditor. The auditor will complete a final audit report within 30 business days after the auditee’s response. OCR will share a copy of the final report with the audited entity.

While conducting desk audits of covered entities, OCR will initiate and complete desk audits of selected business associates. OCR will share a copy of the final report with the audited business associates.

**On-site audits:** As with the desk audits, entities will have 10 business days to review the draft findings and provide written comments to the auditor. The auditor will complete a final audit report for each entity within 30 business days after the auditee’s response. OCR will share a copy of the final report with the audited entity.

6. **After the audits**

OCR views audits as a compliance improvement activity. As such, OCR stated that generally it will use the aggregate results to determine what types of technical assistance should be developed and what types of corrective action would be most helpful. OCR stated that it will also develop tools and guidance to assist the health care industry in compliance self-evaluation and in preventing breaches.

Should an audit report indicate a serious compliance issue, OCR has stated that it may initiate a compliance review to further investigate.

While OCR will not post a listing of audited entities or the findings of an individual audit which clearly identifies the audited entity, under the Freedom of Information Act (FOIA) OCR may be required to release audit notification letters and other information about these audits upon request by the public. In the event OCR receives such a request, OCR stated that it will abide by the FOIA regulations.
Takeaways and tips

- Watch your email: OCR will be sending notification via email and the emails may be incorrectly classified as spam. If your CBHO’s spam filtering and virus protection are automatically enabled, check your junk or spam email folder for emails from OCR.

- Respond to information requests: If an entity does not respond to requests for information (including address verification, the pre-screening audit questionnaire and the document request of those selected entities), OCR will use publically available information about the entity to create its audit pool. An entity that does not respond to OCR may still be selected for an audit or subject to a compliance review.

- Know your business associates: Be sure your CBHO has correctly identified its business associates, has executed the proper written agreements, and has conducted a HIPAA security risk analysis. OCR will be asking auditees for information on their business associates and is encouraging covered entities to prepare a list of each business associate with contact information so that they are able to respond to this request.


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From Galas to Golf Tournaments: Fundraising Compliance Risks
By: Dianne K. Pledgie, Esq., Feldesman Tucker Leifer Fidell LLP

Whether your community behavioral health organization (CBHO) holds a black-tie gala, a golf tournament geared to local businesses, or a 5K walk/run to bring awareness to mental health issues, fundraising can take a variety of shapes and can provide vital support for the budget of a non-profit organization. Soliciting financial contributions from individuals and private businesses also carries with it the prospect of substantial financial exposure and possibly legal exposure. This article provides an overview of the applicable laws, regulations and compliance concerns related to fundraising for non-profit organizations.

Applicable state and federal laws, rules and regulations

Non-profit fundraising is governed by a web of state and federal laws, rules and regulations, making a complex regulatory environment for mission-based organizations.

State regulations and laws

The primary regulation of charitable fundraising occurs at the state, and sometimes local, level. Most states (and some local governments) have enacted legislation regulating the solicitation of charitable contributions. Sanctions for violating these statutes include criminal and civil penalties.

Typically, state registration statutes require a charity to provide, at a minimum, the names and addresses of its Board of Directors, proof that it is recognized by the Internal Revenue Service (“IRS”) as a Section 501(c)(3) organization, and recent financial information, along with a filing fee. While the financial information may be as simple as a copy of the organization’s most recent IRS information return (Form 990), some states require an audited financial statement, depending upon how much is raised through solicitations to the public. Some states also require an annual renewal of registration. Most states exempt certain types of organizations, such as religious groups or organizations that raise less than a threshold amount, e.g., $5,000, through solicitations to the general public.

Internal Revenue Code

The Internal Revenue Code governs when a contribution is tax deductible by the donor. Only contributions to a Section 501(c)(3) charity are tax deductible. Further, a contribution is tax deductible only if it is a true gift, which is defined as the transfer of
money or property without “adequate consideration.” If a donor receives something of value in return for the contribution, the contribution is only partially deductible (or may not be deductible at all) depending on the circumstances. Fundraising activities where this issue can come into play include:

- **Events, such as gala dinners, concerts, and performances.** The IRS presumes that a contribution is not deductible if a donor receives anything of value from a charity in return for the contribution. Payments which are partly gifts and partly in consideration for goods or services are known as “quid pro quo contributions.” Only the value of the contribution that exceeds the fair market value of anything that the charity provides in return for the payment is tax deductible. For example, if a donor purchases a ticket to your CBHO’s gala dinner for $250 and the value of the food and drinks is $100, only $150 of the donor’s ticket price is deductible by the donor.

The IRS expects that a charity will inform donors of the amount of their contribution that is deductible, if any (and requires the charity to provide a written statement to the donor if the quid pro quo contribution is $75 or more). In order to do so, the charity must make a reasonable determination of the fair market value of the benefit that the donor will receive in exchange for the contribution and do so prior to soliciting the contribution. Note that this applies regardless of whether the benefits or items provided by the charity to the donor were themselves donated to the charity. The fair market value of the benefits or items controls.

- **Auctions.** The fair market value of all items donated for an auction should be marked on the item and printed in any brochure or catalog that describes the items up for auction. Only the amount of the purchase price that exceeds the fair market value is deductible. For example, if your CBHO auctions a $250 laptop and a donor pays $300, the donor may only deduct $50 of the amount paid for the laptop.

- **Raffles and lotteries.** The cost of a raffle or lottery ticket is not deductible. Because lottery and raffle proceeds are taxable income to the winner, a charity must report the winnings to the IRS and, in some cases, must withhold income tax from the winner’s proceeds.

- **Token items.** The IRS allows the full value of a contribution to be deducted (and the charity does not have to assign a fair market value) if the item or benefit provided in return for a contribution is “inconsequential” or only of token value. IRS guidelines establish a “safe harbor” for items that meet certain financial criteria, the amounts of which are adjusted annually.

CBHOs and other charitable organizations that receive a contribution of $250 or more (in cash or property) must acknowledge the contribution in writing before the donor files his or her tax return on which the deduction is claimed. Without an acknowledgement of the gift, the donor will not be able to deduct the contribution.
**Corporate sponsorships**

With respect to corporate sponsorship, the IRS draws a line between activities that constitute “advertising” activities and activities that merely acknowledge the sponsor’s support. Revenue that an organization receives for advertising is subject to unrelated business income tax. Under the federal tax regulations, corporate support will not be taxable to a charitable organization if the charitable organization observes certain guidelines to ensure that the sponsorship is not considered advertising.

**Financial support from vendors and suppliers**

CBHOs should be especially careful in soliciting or accepting support from vendors/suppliers when the goods/items of such vendors/suppliers are paid for, in whole or in part, by federal health care programs. Under the federal Anti-Kickback Statute, it is a criminal offense to solicit or receive remuneration, i.e., anything of value, if one of the purposes is to induce or reward the doing of business paid for by a federal health care program.

The Office of Inspector General (“OIG”) has issued an Advisory Opinion approving a sponsorship arrangement between a charitable organization and its vendors based on the following: (1) the event was a legitimate fundraising event; (2) the group of potential sponsors solicited represented a broad-based pool of civic leaders and business sources, many of whom had little or no connection to the organization; and (3) the organization certified that it did not take the event sponsorship into account in awarding or renewing contracts or in purchasing items or services. Although the Advisory Opinion does not constitute a legally binding precedent, the factors cited should be considered if a charitable organization intends to solicit and accept donations from vendors/suppliers.

**Recommendations**

Fundraising can provide important financial support for non-profit organizations. CBHOs should keep the following key points in mind:

- Become familiar with any state or local law covering fundraising activities, in particular, registration requirements.
- Inform donors as to the deductible amount of their contribution if they receive anything of value in return: Inform the purchaser of the deductible amount in any publicity releases and on the event ticket itself. Merely stating that the ticket is “deductible to the extent permitted by law” is not sufficient disclosure. Avoid using any terms on tickets or in publicity that would suggest that the entire purchase price is deductible (or, in the case of raffle or lottery tickets, that any part of the ticket is deductible).
- Consider whether a prospective sponsor’s products and business values are consistent with the organization’s mission. It is also wise to conduct a reasonable “due diligence” inquiry into the reputation, background, and business practices of a potential corporate sponsor.
• Plan any fundraising program that involves soliciting vendors for contributions in accordance with the factors noted by the OIG, particularly the importance of mounting a broad-based appeal.

• Carefully consider the risks involved with the use of internet-based technology for fundraising. Federal and state regulators are struggling to keep up, particularly in assessing how (or if) existing laws and regulations apply. It is extremely important for non-profit organization engaged in internet-based fundraising to keep themselves apprised of developments in this area.

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Fundraising: Sample Policy and Procedure

It is the policy of [CBHO name] ("CBHO") to conduct all fundraising activities (including accessing private philanthropy and corporate sponsorship) in a manner that maximizes access to funds while minimizing financial and legal exposure pursuant to applicable federal and state laws and regulations governing charitable fundraising and solicitation.

Procedure.¹

1. **Registration.** CBHO, through its Executive Director, will file appropriate registration forms (along with required financial documentation) in all states in which the CBHO intends to conduct fundraising activities. If the CBHO intends to conduct fundraising activities in more than one state, to the extent permitted by state law, the CBHO will file the Uniform Registration Statement in lieu of the state-specific registration form.

2. **Tax deductions.** The CBHO will conduct all fundraising activities in accordance with applicable Internal Revenue Code rules governing when and the extent to which a contribution is tax deductible.

   a. **Fundraising events.** If a donor receives anything of value in return for a contribution (a "quid pro quo contribution"), the CBHO will make a reasonable determination of the fair market value of the benefit received by the donor in advance of the solicitation. The CBHO will inform all donors of the specific amount of their contribution that is deductible, if any. If the CBHO receives a quid pro quo contribution of $75 or more, it will provide the donor with a written statement that: (i) informs the donor that the amount of the contribution that is tax deductible is limited to the amount that the contribution exceeds the value of the goods or services that the donor receives, and (ii) provides the donor with a good faith estimate of the value of the goods and services received.

   b. **Auctions.** If the CBHO holds an auction, it will distribute a brochure or catalog describing each item up for auction, including its fair market value.

   c. **Raffles and lotteries.** The CBHO will report winnings of $600 or more from raffles and lotteries to the IRS and, if the proceeds exceed $1000, will withhold income tax equal to 20% of the proceeds.

The requirement to establish the fair market value of any benefit received by a donor does not apply to token items of inconsequential value, based upon the then current guidelines published by the IRS.

¹ Authors’ note: Using the following sample as a guide, CBHOs should tailor the procedure to reflect their own structures and operations.
If a donor contributes a gift of $250 or more, the CBHO will provide the donor with a written acknowledgment of the contribution before the donor files his or her tax return on which he or she will claim a deduction for such contribution.

3. Corporate sponsorship. The CBHO’s Board of Directors will establish guidelines for soliciting financial support from businesses, including any businesses that are “off limits.” The CBHO will conduct reasonable “due diligence” into the background and business practices of a potential corporate sponsor. If the CBHO determines that the potential sponsor is appropriate for the CBHO, the CBHO may:
   a) Acknowledge the sponsor’s support by displaying its name, logo and slogan;
   b) Include value-neutral descriptions of the sponsor’s product line and a list of locations, telephone numbers, website address, and brand or trade names;
   c) Allow the sponsor to display or distribute samples of its products in conjunction with a sponsored event; and/or
   d) Identify the sponsor as the “exclusive” sponsor of an event, so long as the sale, distribution or use of competing products is not limited in connection with the sponsorship.

4. Financial support from vendors/suppliers. The CBHO may solicit and accept financial support from vendors/suppliers, so long as such activity is conducted in accordance with the requirements of the federal Anti-Kickback Statute. When soliciting vendors/suppliers, the CBHO will:
   a) Ensure that the group of potential sponsors solicited represents a broad-based pool of civic leaders and business sources and
   b) Certify that it will not take any support provided by vendors/suppliers into account in awarding or renewing contracts or in purchasing items or services.

5. Internet fundraising. If the CBHO uses internet-based fundraising techniques, it will ensure that the CBHO is registered in all states in which the internet site is accessed. The CBHO will establish appropriate security measures to protect, among other things, donor lists and online credit card transactions.

6. Use of federal grant funds. The CBHO will not use federal grant funds for fundraising purposes.

This policy and procedure shall be periodically reviewed and updated consistent with the requirements and standards established by the Board of Directors and CBHO management, federal and state laws and regulations, and applicable accrediting and review organizations.
Responsible parties:

Signature ___________________________ Date ___________

Executive Director

Signature ___________________________ Date ___________
Emerging Compliance Hotspots for CCBHCs  
Part 3: Overview of the Certification Criteria  
By: Susannah Vance Gopalan, Esq., and Elizabeth Karan, Esq., Feldesman Tucker Leifer Fidell LLP

As part of establishing the Certified Community Behavioral Health Clinics (CCBHC) demonstration, Section 223 of the Protecting Access to Medicare Act (PAMA) of 2014 requires the U.S. Department of Health & Human Services (HHS) to establish a process for the certification of CCBHCs. Within HHS, the Substance Abuse and Mental Health Services Administration (SAMHSA) has identified broad criteria describing operational requirements for organizations to be certified as CCBHCs. States will tailor the criteria and, ultimately, certify organizations as CCBHCs. This article provides a brief overview of the CCBHC criteria including arrangements with other entities to provide services and care coordination.

Certification Criteria

As defined in PAMA, CCBHCs must comply with criteria in six areas:

1. **Staffing**

CCBHC staff must be credentialed, certified, and licensed professionals with adequate training in person-centered, family-centered, trauma-informed, culturally-competent, and recovery-oriented care. In addition, the medical director of the CCBHC must be a psychiatrist unless there is a documented behavioral health professional shortage in the service area as determined by the Health Resources and Services Administration (HRSA).

2. **Availability and Accessibility of Services**

CCBHCs must offer services in a manner accessible and available to individuals in their community. Important elements of this criterion include: access to services at times and places convenient for the population served; prompt intake; and consumer choice in treatment planning and services. CCBHCs must have crisis management services that are available 24 hours a day. Services must be provided on a sliding fee scale to ensure they are accessible to low-income individuals, and CCBHCs cannot reject or limit services based on a patient’s ability to pay or place of residence. Additionally, guidance indicates that states should consider other elements that would further the statutory objectives, such as in-home supports, telehealth, and mobile units.

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3. *Care Coordination*

CCBHCs must provide patients with care coordination. The demonstration uses the federal Agency for Healthcare Research and Quality definition of care coordination, which is: “deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient’s care to achieve safer and more effective care.” According to SAMHSA, this means the patient’s needs and preferences are known ahead of time, communicated at the right time, to the right people, and that this information is used to provide safe, appropriate, and effective care to the patient. CCBHCs must coordinate care across settings and providers to ensure seamless transitions for patients across the full spectrum of health services, including acute, chronic, and behavioral health needs. To accomplish care coordination and other goals of the demonstration, CCBHCs must have in place partnerships and formal contracts with other providers and agencies in the community (discussed further below as Care Coordination Agreements).

4. *Scope of Services*

CCBHCs must provide nine required services. States have some flexibility to shape the scope of services within the required areas to align the program with the state Medicaid plan. Section 223 of PAMA lists the required services, including:

- Crisis mental health services, including 24-hour mobile crisis teams, emergency crisis intervention services, and crisis stabilization;
- Screening, assessment and diagnosis;
- Person-centered treatment planning or similar processes;
- Outpatient behavioral health services;
- Outpatient primary care screening and monitoring of key health indicators and health risk;
- Targeted case management;
- Psychiatric rehabilitation services;
- Peer and family supports; and
- Intensive community-based outpatient behavior health care for veterans and members of the US Armed Forces.\(^3\)

The certification criteria mandate that the CCBHCs directly provide four services: timely crisis behavioral health services; screening, assessment, and diagnosis, including risk assessment for behavioral health conditions; person-centered and family-centered treatment planning; and outpatient mental and substance use disorder services. In general, CCBHCs must directly provide crisis behavioral health services unless a “state-sanctioned alternative” exists.

Some required services may be facilitated with technology. For example, preliminary screenings may be conducted over the telephone. SAMHSA guidance notes that in-person

\(^3\) PAMA § 223(a)(2)(D).
Screenings are preferable but, particularly in emergency situations, telephonically conducted evaluations are allowed.

The remaining five required CCBHC services may be provided through formal contract relationships with other organizations (discussed further below as Designated Collaborative Organizations). However, the guidance suggests that CCBHCs should be designed so most services are provided by the CCBHC rather than with other organizations.

5. Quality and Other Reporting

CCBHCs are expected to use data collection and reporting for assessment and improvement of quality. PAMA requires CCBHCs to report encounter data, clinical outcomes data, quality data, and such other data that HHS requires. States may also require the use of consumer evaluations to assess community involvement in services design and delivery.

6. Organizational Authority

CCBHCs should have demonstrated capacity and capability to meet the CCBHC criteria. CCBHCs may be non-profits, local government entities, or agencies under tribal authority. A non-profit organization with multiple clinics may be a CCBHC as long as the components of the non-profit satisfy the criteria for a CCBHC. For example, one component of the non-profit may be the CCBHC while another component may not be certified as a CCBHC.

Conclusion

Although the CCBHC demonstration comes with significant challenges, the CCBHC model is well-positioned for expansion. Currently the CCBHC demonstration will not be broadly implemented; however, both the President and members of Congress have proposed expansion of the CCBHC program. In the President’s proposed budget for fiscal year 2017, the request included estimated funding of $110 million to add six additional states to the CCBHC demonstration program. In February 2016, members of the House and Senate introduced related bills which would expand the CCBHC demonstration program to all 24 planning grant states.⁴ With continued support by stakeholders, the CCBHC demonstration may provide an important path for behavioral health providers preparing for the future and looking for new opportunities to improve care and reimbursement.

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⁴ See, Expand Excellence in Mental Health Act, S.2525, 114th Cong.; and Expand Excellence in Mental Health Act of 2016, H.R.4567, 114th Cong.
New Mexico’s Suspensions of Medicaid Payments to Providers: Recent Developments Demonstrate Matters Remain Unresolved

By: Adam J. Falcone, Esq., Feldesman Tucker Leifer Fidell LLP

Over the last three years, Compliance Watch has published several articles and updates regarding New Mexico’s use of regulatory authority to suspend Medicaid payments to 15 behavioral health providers based on fraud allegations, and subsequent referral of the allegations to the state Attorney General (AG) for investigation.

Since our last update in July/August 2015, there have been additional developments that are instructive for behavioral health providers in other states. This article provides an overview of the past events and describes three recent developments.

**Background**

New Mexico’s Medicaid agency contracted with United Behavioral Health ("United") to arrange and pay for behavioral health services from July 1, 2009, to Dec. 31, 2013 under a roughly $370 million annual contract. In October 2012, United notified the Medicaid agency of some suspicious billing activity among providers in its network.

In February 2013, New Mexico’s Medicaid agency contracted with a national firm, Public Consulting Group (PCG), to audit the 15 behavioral health providers. The audit firm does similar work for other states, either directly for Medicaid agencies or indirectly for contractors of Medicaid agencies, such as Recovery Audit Contractors (RACs). (For more information on RACs, see Compliance Watch articles “Recovery Audit Contractors Set to Expand to Medicaid Program” published in July/August 2011 and “RAC Audits: Protection Strategies” published in May/June 2013).

After reviewing the documentation supporting 150 randomly sampled claims from each provider, PCG reported that the providers’ documentation did not comply with New Mexico’s billing requirements. For instance, PCG found insufficient documentation for: the training of community support workers, progress notes related to the timeliness of clinical assessments and treatment plans, consumer consents for medications, services rendered, start and stop times, and presence of treatment team members.
Extrapolating from its findings over a three and a half year period, PCG concluded that there had been more than $36 million in overpayments for the 15 providers, amounting to 15% of total payments from the Medicaid program. After PCG conducted its audit, New Mexico’s Medicaid agency suspended payments to all 15 providers and referred the matter to the Attorney General’s Office.

In suspending payments to the behavioral health providers, New Mexico relied on regulations issued by Centers for Medicare and Medicaid Services (“CMS”), codified at 42 C.F.R. § 455.23, which incorporated new terminology from the Affordable Care Act to require state Medicaid agencies to suspend payments, absent good cause, to a provider for which there is a pending investigation of a credible allegation of fraud. (For more information on this regulation, see Compliance Watch article “Payment Suspension for Fraud” published in Nov/Dec 2012).

After receiving media inquiries about the payment suspensions, New Mexico asserted that it was barred from considering grounds for good cause prior to imposing the payment suspension. To understand why the State’s assertion is questionable, readers may find it helpful to review the article “New Mexico’s Suspensions of Medicaid Payments to Providers: An Examination of the State’s Position” (Compliance Watch, Sept/Oct 2013).

The payment suspensions in New Mexico threatened the financial viability of many of the providers, which relied on Medicaid for the majority of their revenue. Following the payment suspensions, New Mexico’s Medicaid agency subsequently recruited at least two behavioral health providers from Arizona to replace providers that could no longer continue to furnish services.

Since the payment suspensions, ten of the providers have sued the New Mexico Medicaid agency, alleging that the agency violated their due process rights when it withheld payments indefinitely without an opportunity to appeal the state’s decision. A New Mexico trial court ruled in one of the providers’ favor in January 2015.6

**Arizona Company Sues United Behavioral Health**

La Frontera Center Inc. was one of the behavioral health providers brought in from Arizona to replace several of the 15 former providers. La Frontera replaced two major providers — Southwest Counseling Center Inc. and Families & Youth Inc. in Las Cruces, NM.

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5 See Section 6402(h)(2) of the Patient Protection and Affordable Care Act (Affordable Care Act).

In February 2016, La Frontera sued United, alleging the insurer made "false, misleading and fraudulent statements and representations of fact or failed to disclose material facts" between November 2012 and November 2014, according to the lawsuit.\(^7\)

La Frontera alleges that United engaged in a cover-up of its own failings, such as having defective systems for processing claims and being unable to fulfill its contractual obligations to the State of New Mexico. As part of its cover-up, La Frontera alleges that United blamed the 15 behavioral providers for fraud through allegations of non-compliance with insurer’s claims processing system.

Based on several legal theories, including breach of contract, negligent and fraudulent misrepresentation, and breach of good faith and dealing, La Frontera is seeking almost four million dollars for unpaid claims for the behavioral health services it provided during its first six months in New Mexico, contract damages in excess of twelve million dollars, punitive damages, and legal fees.

**Attorney General Clears Behavioral Health Providers of Fraud Allegations**

Following the Medicaid agency’s referral of the behavioral health providers to the AG’s Office in 2013, the AG proceeded to investigate the allegations. In 2015, the first three behavioral health providers were cleared of allegations of fraud.

In February 2016, ten of the remaining twelve providers were cleared of fraud by New Mexico Attorney General Hector Balderas. The AG found some regulatory violations but no pattern of fraud.\(^8\)

In a letter to state legislators, AG Balderas stated that he “came to different conclusions on many of the alleged violations” and “ultimately did not find that the violations . . . reflected a deliberate or intentional pattern of fraud.”\(^9\)

In April 2016, AG Balderas cleared the last two behavioral health providers of Medicaid fraud.\(^10\) Similar to his February letter, AG Balderas stated that “although the investigation

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\(^7\) [http://nmpolitics.net/index/wp-content/uploads/2016/03/LaFronteraComplaint.pdf](http://nmpolitics.net/index/wp-content/uploads/2016/03/LaFronteraComplaint.pdf)


\(^9\) *Id.* at p. 2.

identified some regulatory violations, we were unable to substantiate a deliberate or intentional pattern of fraud."

AG Balderas has made all of his office’s investigations available on the website of the Office of the Attorney General at http://www.nmag.gov/2013-behavioral-health-audit.aspx. He also released the 2013 PCG audit reports in full with limited redactions.11

As state auditor, Balderas had found in 2013 that the New Mexico Medicaid agency removed language in the PCG audit reports that said that its audit “did not uncover what it would consider to be credible allegations of fraud, nor significant concerns related to consumer safety.”12 The Medicaid agency’s finding of “credible allegations of fraud” served as the legal basis for the providers’ payment suspensions and subsequent referrals to the Attorney General’s Office for investigation.

NM Delegation Introduces Legislation in Congress to Protect Due Process Rights

As a consequence to the payment suspensions of the behavioral health providers, U.S. Senators Tom Udall and Martin Heinrich, and U.S. Representatives Ben Ray Luján and Michelle Lujan Grisham introduced the Medicaid Program Integrity Enhancement Act of 2016 (S. 2701/H.R. 4802) on March 17, 2016.

The legislation requires state agencies to consider the impact on beneficiary access to care prior to suspension of Medicaid payments to providers based on credible allegation of fraud, and enhances due process protections for providers before and after payment suspensions occur.

Specifically, the Medicaid Due Process Integrity Act would:

- Prevent unnecessary payment suspensions by requiring a Medicaid agency to consult with a state attorney general on the credibility of allegations prior to suspending payments.
- Protect beneficiary access to care by requiring a state to consider the impact a payment suspension may have on beneficiary access to care prior to withholding payments.
- Guarantee due process of law by requiring states to cease payment suspensions where an investigation has ended after 18 months.
- Require states to create an appeal process for providers to challenge charges against them.

The Medicaid Due Process Integrity Act has the endorsement of the National Council for Behavioral Health. “Fraud and abuse in Medicaid must be taken very seriously. Yet, as the cases in New Mexico show, upstanding providers must be protected from unsubstantiated allegations,” said Linda Rosenberg, President and CEO of the National Council for Behavioral Health. “Just as in any part of our legal system, individuals and organizations deserve to know the allegations against them and to have those allegations investigated and resolved in a speedy manner so that we can prevent future crises like that seen in New Mexico.”

The National Council lauded the bill’s inclusion of a requirement that states consider the effect on beneficiary access to care before taking action to suspend providers’ Medicaid payments. “In the New Mexico case, patients’ access to care evaporated practically overnight,” said Rosenberg. “This is especially galling because at the end of an unreasonably protracted investigation, the providers were found to have done no wrong.”

In February, 2016, prior to introducing the legislation, New Mexico’s Congressional delegation sent a letter to U.S. Health and Human Services Secretary Sylvia Burwell calling for a thorough investigation of the findings in the New Mexico Attorney General’s report that cleared the providers of fraud.\(^ {13}\)

**Conclusion**

In light of the exoneration of all 15 behavioral health providers by the New Mexico AG, and the lawsuit against United by one of the Arizona behavioral health providers, litigation regarding this matter is far from over.

For behavioral health providers in other states, one lesson to draw from their peers in New Mexico is how documentation and billing issues can be viewed by certain parties as fraud, and turn into payment suspensions without any due process of law.

Given the impact on beneficiary access to behavioral health services when payment suspensions occur, providers must be vigilant in complying with documentation and billing rules, and be ready to move aggressively—in the political, judicial and administrative arenas, as necessary—when there are allegations of fraud because a provider’s very existence is at stake.

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\(^ {13}\) Letter to Secretary Burwell (Feb. 17, 2016), available at: https://www.scribd.com/doc/299790684/Delegation-Calls-for-Federal-Investigation-Into-NM-Human-Services-Department-Suspending-Medicaid-Payments-to-Behavioral-Health-Providers
SAMHSA Proposes Modernization of Federal Substance Use Privacy Regulations

By: Carrie Bill Riley, Esq., Feldesman Tucker Leifer Fidell LLP

When the Substance Abuse and Mental Health Services Administration (SAMHSA) promulgated the Confidentiality of Alcohol and Drug Abuse Patient Records regulations, 42 C.F.R. Part 2 (Part 2) in 1975, patient health information was typically exchanged by mail.

Today's health care landscape is considerably different, with new models of integrated care that are built on a foundation of information sharing to support coordination of patient care, the development of an electronic infrastructure for managing and exchanging patient information, and a new focus on performance measurement within the health care system. Several components of Part 2 are in tension with the information sharing trends that are the hallmark of today's care coordination initiatives.

Given the extensive changes to our nation’s health system and advancements with information technology, SAMHSA published a Proposed Rule on February 9, 2016 to modernize Part 2. Through the Proposed Rule, SAMHSA attempts to facilitate information sharing within new models of integrated care, while also tackling the privacy concerns of patients seeking treatment for substance use disorders (SUD).

SAMHSA expects the proposed changes will result in a decrease in the burdens associated with several aspects of Part 2, including patient consent requirements. In addition, SAMHSA anticipates that more individuals with SUDs will participate in organizations that facilitate the exchange of health information (e.g., health information exchanges (HIEs)) and organizations that coordinate care (e.g., accountable care organizations (ACOs)), leading to increased efficiency and improved quality in the provision of health care for this population.

This article highlights features of the Proposed Rule that are particularly notable and of interest to community behavioral health organizations (CBHOs).

Defining Part 2 Programs

Under the current regulations, an organization or individual must comply with Part 2 if it (1) is federally assisted and (2) is a “Program.” Program is defined as:

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• An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment;
• An identified unit within a general medical facility which holds itself out as providing and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment; or
• Medical personnel or other staff in a general medical facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers.

The Proposed Rule does not define “general medical facilities.” It does, however, state that hospitals, trauma centers and federally qualified health centers would generally be considered “general medical facilities.” It further notes that Part 2 is not intended to extend to the provision of substance use disorder treatment services as an incident to the provision of general health care.

This clarification suggests that a CBHO may be considered a “general medical facility” if it furnishes a broad scope of services beyond SUD diagnosis, treatment, and/or referral. For example, if a CBHO furnishes behavioral health services and primary care services, and the provision of SUD diagnosis, treatment and/or referral is an incident to its provision of such general health care, then the CBHO may qualify as a “general medical facility.” As a general medical facility, the CBHO would only be subject to Part 2 if (1) it has an identified unit that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or (2) it has staff whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and such staff is identified as such specialized staff by the general medical facility.

Defining Substance Use Disorder

As noted above, the current regulations protect the exchange of records pertaining to the diagnosis and treatment for “alcohol or drug abuse.” SAMSHA acknowledges that such term is vague, and proposes to replace “alcohol or drug abuse” with “substance use disorder,” which it defines as “a cluster of cognitive, behavioral, and psychological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal.” In addition, SAMHSA proposes to revise the regulations to clarify that “substance use disorder” does not include addictions to tobacco or caffeine, which are also customarily referred to as substance abuse.

Expanding Qualified Service Organization Services

Part 2 currently permits Programs to disclose patient identifying information, including substance use disorder records, to a qualified service organization (QSO) without a patient’s consent. QSOs provide certain services (such as data processing, bill collecting,
dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services) to a Program consistent with a qualified service organization agreement (QSOA). To become qualified, the QSO must enter a written agreement with the Program in which it acknowledges that it is bound by the Part 2 confidentiality regulations.

In order to improve health outcomes, many organizations are turning to population health management organizations to monitor and identify patients. In the Proposed Rule, SAMHSA proposes to include population health management to the list of services that may be furnished through a QSO without a patient’s consent. Notably, population health management would not include care coordination which has a patient treatment component. While the QSOA would allow for sharing of SUD information for population health management, the entire organization (including case managers, providers, or hospitals) would not have access to the patients’ Part 2 information under the QSOA.

Accordingly, under the Proposed Rule, a CBHO would be able to participate in population health management activities through a QSO, thereby providing the QSO with patients’ Part 2 information, without obtaining patients’ consent. Such activities, however, would have to be set forth in a QSOA and the QSO must independently comply with Part 2.

Changing Consent Requirements

“To Whom”: Currently, a valid patient consent form must include the name or title of the individual or the name of the organization to which the disclosure will be made. Part 2 requires this specificity so that the patient may identify, at the point of consent, exactly which entities and individuals they are authorizing to receive their SUD-related information.

This required level of specificity has made it difficult for Part 2 Programs to participate in organizations that facilitate the exchange of health information or coordinate care, such as HIEs and ACOs, because the pool of participating providers often changes. As an example, if a new provider joins an HIE or ACO after the patient signs a consent, and the patient goes to that new provider for SUD treatment, the new provider is required to obtain the patient’s consent to receive the patient’s SUD-related information.

To encourage participation in organizations that facilitate the exchange of health information or coordinate care, SAMHSA proposes to revise the consent requirements to permit, in certain circumstances, a disclosure to an entity without a treating provider relationship with the patient (e.g., an ACO or HIE) and a general description of the individuals or entities to which a disclosure is made.
Specifically, under the Proposed Rule, a patient may indicate that he/she consents to disclosures to an entity that facilitates the exchange of health information, such as an ACO or an HIE, which must be named, and:

1. The name of an individual participant(s);
2. The name(s) of any entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; or
3. A general designation of an individual or entity provider(s) or a class of participants that must be limited to have a treating provider relationship with the patient whose information is being disclosed.

As an example, a patient could indicate on their consent form that disclosures may be made to the HIE (which must be named) and “my current and future treating providers.” The general designation could not, however, include the function “HIE participants” without providing additional detail.

The amount and kind of information disclosed: Currently, Part 2 requires that the patient consent form include how much and what kind of information is to be disclosed.

SAMHSA seeks to ensure that patients are aware of the information they are authorizing to disclose when they sign the consent form. As part of the Proposed Rule, the patient would be required to explicitly describe the type of SUD-related information that may be disclosed. For example, the Proposed Rule states that a description such as “medications and dosages, including substance use disorder-related medications” would be acceptable, but a broad description, such as “all of my records,” would be inadequate.

List of Disclosures

Currently, Part 2 does not include a means for patients to determine which individuals and entities received their SUD-related records.

The Proposed Rule would permit patients to request from an entity without a treating provider relationship (e.g., an HIE or ACO) a list of entities that received their information pursuant to the general designation within the past two years. Within 30 days of the written request, the entity would have to provide the name of each entity to which the disclosure was made, the date of the disclosure, and a brief description of the patient identifying information disclosed. The brief description of the information disclosed would have to contain sufficient specificity so as to be understandable to the patient.

Because of the information technology challenges associated with obtaining such disclosure information, SAMHSA proposes that this “List of Disclosures requirement” would not become effective until two years after the effective date of the final rule.

Prohibiting Re-disclosure

Under the current regulations information disclosed from records protected by Part 2
cannot be re-disclosed by the recipient unless disclosure is expressly permitted by the written consent of the patient.

According to SAMHSA, there has been confusion as to how much of a patient's record is subject to Part 2. The Proposed Rule would clarify that the prohibition on re-disclosure only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a SUD, such as indicated through standard medical codes, descriptive language, or both. Other health-related information shared by the Part 2 program may be re-disclosed if permissible under other applicable laws.

**Securing and Disposing of Records**

Currently, Part 2 addresses the maintenance, disclosure, access to, use of and disposition of paper records. It does not address electronic records.

Under the Proposed Rule, Part 2 programs must have formal policies and procedures in place for both paper and electronic records. Such policies and procedures must reasonably protect against unauthorized uses and disclosures of patient identifying information and anticipated threats or hazards to the security of patient identifying information. The formal policies and procedures related to record disposition by discontinued programs must provide a process to ensure hard copy and electronic media can be “sanitized” so that they are permanently destroyed and unrecoverable.

**Conclusion**

The public comment period for the Proposed Rule closed on April 11th. SAMHSA has three years from the close of the comment period to issue it in final form, unless it publishes a notice extending the time frame. CBHOs required to comply with Part 2 will be required to come into compliance with any revised regulations by the effective date of the final rule; however, signed consent forms in place prior to the effective date of the final rule would be valid until they expire.

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