HCCA Orlando Regional Conference
340B Program Updates
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Nancy is a Senior Manager in the Deloitte healthcare advisory practice with over 30 years' experience in healthcare management and administration. She has a diverse clinical background as a Registered Nurse, with comprehensive experience in critical care, maternal child health, and home care. Nancy is considered an industry leader when it comes to level of care for the hospitalized patient and CMS guidelines regarding the two midnight rule.

Nancy has served as an expert witness for litigation concerning the medical necessity of inpatient and outpatient services. Nancy has also assisted numerous clients directly and through counsel, in responding to OIG audits, investigations, self-disclosures and preparing for CIAs.
Prior to joining Deloitte, Nancy worked for one of the Centers for Medicare and Medicaid Services, Recovery Auditors.

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What is 340B?

- **The 340B Drug Pricing Program** requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices:
  - More than 13,000 eligible entities participate in program
  - Average savings of 25 - 50% on outpatient prescription drugs

Source: http://www.hrsa.gov/opa/index.html

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Some key elements to maintaining compliance

Adherence to Duplicate Discount requirement
- Medicaid Exclusion file current
- Modifiers, if applicable, applied to all eligible claims
- Adherence to state requirements for Managed Care Organization (MCO) claims

Adherence to Diversion
- Only eligible patients receive 340B drugs

Adherence to GPO Prohibition
- Covered outpatient drugs not purchased on GPO

Maintaining documentation / audit trail
- Current policies and procedures
- Each patient can be traced back to an accumulation

Monitoring
- Regular monitoring of 340B program

Source: https://www.hrsa.gov/opa/programrequirements/

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Establish a monitoring plan
Establish and document a monitoring plan

Considerations:

- Compare the amount of lines in the data feed that was sent to the split-billing software vendor to the amount of lines that were accumulated that day
- Review your accumulations for excessively high and negative accumulations
- Review your WAC purchases and understand why the purchase occurred on the WAC account
- Select a sample of hospital claims and review for the following elements:
  - Where did the prescription originate?
  - Was the location 340B eligible?
  - Is it a Medicaid claim?
  - If Medicaid, was it billed according to applicable state requirements?
  - What is the Office of Pharmacy Affairs (OPA) database 340B ID number of the location?
  - What was the patient status at time of drug administration?
  - Was the medication administered?
  - Which account did it accumulate on? 340B, GPO, WAC
  - Does the NDC that was billed match what was dispensed?

Select a sample of contract pharmacy claims and review for the following elements:
  - Evaluation of patient diagnosis during qualifying event
  - Was the diagnosis related to the drug that rendered the dispensation 340B eligible?
  - Was the qualifying event within XXX days of prescription being written? – This is covered entity specific
  - If the prescription was a refill, was the refill within the last XXX days? -- This is covered entity specific
  - Was the provider eligible?
  - Was the location eligible?
  - Did the prescription have Medicaid as a payor?

If participating in contract pharmacy, are you having annual external reviews?

Source: https://www.federalregister.gov/documents/2015/08/28/2015-21246/340b-drug-pricing-program-omnibus-guidance

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Program updates

Bipartisan Budget Act of 2015

- Concerns that registration of new off-campus Provider-Based Departments (PBDs) may no longer be 340B eligible.
- CMS issued the interim final rule, effective January 1, 2017
- New registrations for 2017 will be eligible for 340B consideration:
  - Hospitals will bill Medicare for services provided in new off-campus PBDs on the institutional claim form using a new modifier to identify the services.
  - Comments on the interim final rule were due to CMS no later than December 31, 2016
- Final rule expected in 2017 to be effective 2018:
  - Watch for potential 340B implications in 2018

Source: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-26515.pdf

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Program updates Continued

Average Manufacturer Price (AMP) Final Rule: Covered Outpatient Drug Reimbursement Finalized February 2016

- This law only impacts Covered Entities (CEs) that have hospital owned retail pharmacies
- Hospital owned retail pharmacies will be required to bill Actual Acquisition Cost (AAC) for all Fee-for-Service (FFS) claims.
- States must submit a State Plan Amendment (SPA) no later than June 30, 2017, to be effective no later than April 1, 2017
- Be proactive and provide feedback to your State Medicaid Agency

Source: https://www.federalregister.gov/documents/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs

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Program updates Continued

Medicaid Managed Care Final Rule finalized in May 2016:

- This law is to prevent duplicate discounts on Managed Care Organization (MCO) claims
- Each state is required to establish a mechanism on how CEs should ensure rebates are not being sought on MCO claims
- This applies to the 340B Program as a whole – hospital-owned retail pharmacies, contract pharmacies, and physician-administered drugs within the four walls of the hospital as well as off-campus departments
- Any MCO contract beginning July 1, 2017 or later, will be required to include this mandate

Source: https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered

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Program integrity

HRSA Results (last updated 11/22/16)
- FY16 – 71 out of 130 (55%) completed audits had adverse findings
- FY15 – 131 out of 200 (66%) completed audits had adverse findings

Common Adverse Findings
- **Diversion**
  - 340B drugs written at an ineligible sites
  - 340B drugs dispensed to inpatients
  - 340B drugs not properly accumulated
- **Incorrect 340B database record**
  - Registered contract pharmacies without written contract in place
  - Offsite patient facilities not listed on database
  - Incorrect entry for primary contact
- **Duplicate Discounts**
  - Inaccurate or incomplete information in the Medicaid Exclusion File
  - Controls not in place to prevent duplicate discounts
- **GPO exclusion violation**
  - Covered outpatient drugs obtained through a group purchasing organization
- **Monitoring**
  - Entity did not provide contract pharmacy oversight

Source: https://www.hrsa.gov/opa/programintegrity/auditresults/fy16results.html
Source: https://www.hrsa.gov/opa/programintegrity/auditresults/fy15auditresults.html

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Repayment to manufacturers for violation
- 67 out of 130 (52%) in FY16
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Termination of contract pharmacies from program
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Termination of 340B status/program
- 0 out of 130 (0%) FY16
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Operational Compliance: Focus on Risk Areas

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- Erin Smith Aebel is board certified as a health law specialist by the Florida Bar. She represents physicians, hospitals and other healthcare providers in business law including fraud and abuse, Stark, HIPAA, and licensure. Erin also advises on a variety of Florida health law issues including the developing medical marijuana law.
- Erin's clients include hospitals, physicians, physician group practices, diagnostic imaging centers, pharmacies, clinical laboratories, and medical spas.
- Erin regularly advises clients on Stark, fraud and abuse, HIPAA and licensure issues arising from joint ventures, acquisitions and changes of ownership. She regularly prepares and negotiates hospital-related agreements, physician employment agreements, and medical director agreements. Erin is frequently involved in licensure and scope of practice issues for her clients, including physicians, weight loss clinics, medical spas, and other providers.
- While at Loyola Law School, Erin was the Articles Editor of the *Loyola Law Review*. She was awarded a Phelps Dunbar scholarship and the Warren E. Mouledoux Editor-In-Chief's award for outstanding law review dedication and service.
- Erin frequently speaks and writes on health care topics. She has been published in *Florida Medical Business* and by the American Health Lawyers Association.

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Overview and Roadmaps

Four areas of focus for our discussion:

1. Billing Compliance and 340B drug programs;
2. Diligence related to bona fide prescriptions;
3. Compliance related to improper inducements to patients and referring physicians;
4. Special Issues for Compounding Pharmacies.

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Billing Compliance for 340B Drug Programs

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Billing Compliance for 340B Drug Programs

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Sanctions

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Diligence Related to Bona Fide Prescriptions

Federal Law – Regulates Controlled Substances:

To dispense controlled substances, a pharmacist must know the requirements for a valid prescription.

- A prescription is an order for medication, which is dispensed to or for an ultimate user (i.e., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).

The prescription must also include:

1. Drug name
2. Strength
3. Dosage form
4. Quantity prescribed
5. Directions for use
6. Number of refills authorized (if any)

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Diligence Related to Bona Fide Prescriptions

- A prescription must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued.
- An individual (i.e., secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature.
- The practitioner is responsible for ensuring the prescription conforms to all requirements of the law and regulations, both federal and state.

Who May Issue

A prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice, i.e., in Florida – Nurse practitioners and physician assistants can prescribe schedule II, III or IV controlled substances since January 1, 2017. (Fla. Stat. § 893.03); and
1. Registered with DEA or exempted from registration (e.g., Public Health Service, Federal Bureau of Prisons, military practitioners), or;
1. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered, provided that additional requirements are set forth in the coding federal regulations are met.

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Diligence Related to Bona Fide Prescriptions

Purpose of Issue:

- A prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.
- The practitioner is responsible for the proper prescribing and dispensing of controlled substances.
- A prescription may not be issued in order for an individual practitioner to obtain controlled substances to be generally dispensed to patients.

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Diligence Related to Bona Fide Prescriptions

Corresponding Responsibility:

- A pharmacist has a corresponding responsibility to ensure the validity of the prescription.
- An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the Controlled Substances Act (21 U.S.C. § 829).
- The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

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Diligence Related to Bona Fide Prescriptions

- A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription.
- Such determination is made before the prescription is dispensed. A pharmacist should not dispense a prescription of doubtful, questionable, or suspicious origin.
- The pharmacist who deliberately ignores a questionable prescription when there is a reason to believe it was not issued for a legitimate medical purpose may be prosecuted, along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.
- Such action is a felony offense, which also may result in the loss of one's business or professional license (see, United States v. Kershman, 555 F. 2d 198 (8th Cir., 1977).

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Diligence Related to Bona Fide Prescriptions

- While the regulations do not provide additional insight about how to exercise corresponding responsibility, the DEA has created the notion that pharmacists must identify (and resolve) certain red flags before a prescription for controlled substances is dispensed.
- Discussions of common red flags can be found in Final Orders issued by the DEA in administrative proceedings and in presentations given by the Agency in public forums.

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Diligence Related to Bona Fide Prescriptions

- Patient Red Flags:

1. Group arrives at the pharmacy with similar prescriptions from the same doctor;
2. Paying cash;
3. Geographic anomalies (i.e., patient travels a long distance to doctor or pharmacy);
4. Shared addresses by customers presenting on the same day;
5. Patient uses street names for drugs (“Xanies”);
6. Patient exhibits drugged behavior;
7. “Doctor shopping” – patient gets prescriptions from multiple doctors.

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Diligence Related to Bona Fide Prescriptions

Red Flags with Prescribers/Prescriptions:

- Prescription written in different colored inks or different handwriting.
- Apparent eraser marks.
- Prescription does not use acceptable standard abbreviations.
- Prescription looks too good – the prescriber's handwriting is too legible.
- "Pattern prescribing" – prescriptions for the same drugs and the same quantities coming from the same doctor;
- Prescribing combinations or "cocktails" of frequently abused controlled substances;
- Prescriptions written by doctors for infirmaries not consistent with their area of specialty;
- Quantity and strength;

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Diligence Related to Bona Fide Prescriptions

- By identifying red flags you are exercising your corresponding responsibility as required by the regulations.
- It is not clear from DEA guidance how many and/or what combination of red flags must be present for a pharmacist to decline dispensing a particular prescription.
- A pharmacist cannot simply defer to the prescribing practitioner and must exercise his/her independent judgment when determining whether a prescription was issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

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Diligence Related to Bona Fide Prescriptions

- Educate your pharmacists, give them training regularly and have checklists for suspicious prescriptions and document your training.
- Know your patients and prescribers.
- Check state databases (prescription drug monitoring programs).
- Manage physician pushback.

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Diligence Related to Bona Fide Prescriptions

- Failure to pay attention to red flags is costly.
- 2013 Walgreens pays 80 million to the government to end a DEA probe into record keeping and dispensing violations.
- Walgreens had failed to maintain proper controls to ensure that it did not dispense drugs to addicts and dealers.
- 2017 Costco will pay in settlement 11.75 million for lax pharmacy controls. From 2012 – 2015 the pharmacy filled prescriptions that lacked valid DEA numbers, filled improper prescriptions outside the scope of a doctor's DEA registration, and failed to maintain accurate dispensing records.

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State Law

You need to comply with both federal and state law concerning prescriptions for controlled substances.

Florida law: Fla. Admin Code § 64 B16-27.831.

- In filling prescriptions for controlled substances, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment.
- Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice.
- Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind.
- Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.

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State Law

General Standards for Validating a Prescription:

- Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacists.
- There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled.
- Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

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State Law

a. When validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.

b. When validating a prescription, the pharmacist shall ensure that all communication with the patient is not overheard by others.

c. When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

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State Law

Minimum Standards Before Refusing to Fill a Prescription:

a. Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and shall attempt to validate the prescription by performing the following:

1. Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription;

2. Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.

a. In lieu of either subparagraph 1. or 2. , but not both, the pharmacists may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.

b. In the event that a pharmacist is unable to comply with paragraph (1) due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.

Duty to Report: If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health.

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Compliance Related to Improper Inducements and Referring Physicians

Law

- The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program.
- Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated.
- By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction.
- For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

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Compliance Related to Improper Inducements and Referring Physicians

- The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011).
- Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both.
- Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid.

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Compliance Related to Improper Inducements and Referring Physicians

- Where a party violates this law the OIG may initiate administrative proceedings to impose civil monetary penalties.
- The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs.
- A Pharmacy should not give anything of value to a physician who writes prescriptions to the pharmacy.
- The only financial arrangements with a physician must meet both a Stark-Exception and an anti-kickback law safe harbor if there are any prescriptions for drugs covered by Medicare or Medicaid, i.e., physician owns inhouse pharmacy, or physician has an investment in a pharmacy management company.

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Compliance Related to Improper Inducements and Referring Physicians

- Civil monetary penalties may be assessed against any person who offers or transfers remuneration to a Medicare or state health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program (including Medicaid).
- The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs.
- "Remuneration" includes "transfers of items or services for free or for other than fair market value." The OIG has previously taken the position that "incentives that are only nominal in value are not prohibited by the statute," and has interpreted "nominal in value" to mean "no more than $10 per item, or $50 in the aggregate on an annual basis."

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Compliance Related to Improper Inducements and Referring Physicians

- The Affordable Care Act amends the Act's statutory definition of "remuneration" applicable to section 1128A(a)(5) by adding a new exception as subsection (G) for rewards offered by retailers that meet certain criteria.
- Pursuant to the ACA, retailer rewards do not constitute "remuneration" under the CMP if:

1. The rewards consist of coupons, rebates, or other rewards from a retailer;
2. The rewards are offered or transferred on equal terms available to the general public, regardless of health insurance status; and
3. The offer or transfer of the rewards is not tied to the provision of other items or services reimbursed, in whole or in part, by the Medicare or Medicaid programs.

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Compliance Related to Improper Inducements and Referring Physicians

OIG Advisory Opinion No. 12-DA (May 2012)
OIG Advisory Opinion No. 12-14 (October 2012)

- Under these opinions, the OIG would not sanction the pharmacies that gave rewards because they comply with the ACA exception.
- OIG Advisory Opinion No. 12-05 – Approved a consumer rewards program with in-store and independent pharmacies. Customers who signed up earned gasoline discounts based on customers who signed up for the Requestor's free loyalty card.
- OIG Advisory Opinion No. 12-14 – The super market with pharmacies offered customers a free preferred customer card ("store card"). Any person with a store card is entitled to benefits such as special pricing and discounts, and opportunity to earn discounts at a gas station. The customers can accrue gasoline discounts based on payments, co-pays, and deductibles, as well as in store purchases.

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Special Issues with Compounding Pharmacies – Fraud Cases

- Coverage of compounded drugs:
  - Certain federal payors (i.e., TRICARE) may cover these drugs. Medicare Part D only provides coverage for compounded drugs that are prescribed for a "medically accepted indication." Reimbursement is limited to FDA approved component(s) of the compounded medication. Most compounded drugs are made from bulk powders, which are not FDA approved, and are not covered under Part D. Coverage of compounds under Part C is not clearly defined – seems to be up to the individual insurer to set the payment policy.
- Kickback: Implicated If physicians have ownership interest in the compounding pharmacies and they refer to those pharmacies.
- Potential False Claims actions based on medical necessity for compounding laws- are the drugs actually efficacious?

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Special Issues with Compounding Pharmacies – Fraud Cases

Compounding pharmacies have been subject to recent scrutiny:

- FCA settlement of $3.8 million with a compounding pharmacy in Florida (Medi Mix, LLC) the top biller for compounded pain medication (to TriCare) for submission of claims to TRICARE for compounded drugs referred from a physician whose wife was an officer of the pharmacy and the drugs prescribed were not "individually prescribed or dispensed by a bona fide treating physician for a specific medical condition. . . ." The Department of Defense Special Agent in Charge stated that "fraud and abuse by pharmacies and medical providers for compounded pain prescriptions [are] a significant threat. . . ."
- In October, 2014, government agents raided OK Compounding Pharmacy located near Tulsa pursuant to a search warrant. The search was based on a multi-agency health care fraud investigation of the compounding pharmacy. No arrests were made at the time this article was published.

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Special Issues with Compounding Pharmacies – Fraud Cases

- In December, 2014, the DEA registration of Westchase Compounding Pharmacy was deactivated following a raid of the Tampa based pharmacy. During the DEA raid, agents seized eleven boxes of controlled substances. Following their DEA registration deactivation, the pharmacy's attorneys obtained a temporary restraining order against the DEA and initiated a suit for the DEA's failure to follow proper raid procedures. However, following a settlement between the parties, the suit was ultimately dropped. The DEA agreed to reinstate the pharmacy's registration under the condition that the pharmacy follow the law. According to the article, there were no criminal charges filed against the pharmacy.

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Special Issues with Compounding Pharmacies – Fraud Cases

- In February, 2016, four northeast Florida physicians who ran a compounding pharmacy settled with the Department of Justice for $10,000,000. The government alleged fraudulent claims submitted to TriCare for compounded medications. Many patients claimed creams not used. Cost of the creams 4-5% of amount billed. Shared up to 40% of revenue with referring physicians. Physicians claimed conducting a research study but no results published and no patients informed.

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GAO Report on Payment Practices of Compounded Drugs – October 2014 Payment Issues

- Why did GAO conduct this report?
  - Compounded drugs and some of their ingredients may not be approved by the FDA, which affects potential payment for these drugs.
  - Members of Congress were concerned Medicare's, Medicaid's, and private health insurers' payment practices created incentives to prescribe compounded drugs.
- What did GAO examine?
  - Medicare, Medicaid, and private health insurance payment programs for compounded drugs dispensed in pharmacies and outpatient settings.
  - CMS's Medicare Part B payment policy and its effectiveness.
- What did GAO find?
  - Payment policies vary across Medicare, Medicaid, and private health insurers.
- Compounded drugs dispensed in pharmacies
  - Claims for these compounded drugs have sufficient information to identify the compounded drug and its ingredients.
  - Allows for payers to determine whether or not the compounded drug and ingredients are covered.

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GAO Report on Payment Practices of Compounded Drugs – October 2014 (Findings & Recommendation)

Compounded drugs dispensed in pharmacies

- Claims for these compounded drugs have sufficient information to identify the compounded drug and its ingredients.
- As a result, payors can readily determine whether or not the compounded drug and its ingredients are covered.

Compounded drugs dispensed in outpatient settings

- Claims for these compounded drugs do not have billing codes and therefore do not have sufficient information to identify the compounded drugs and its ingredients.
- As a result, most payors do not pay for these compounded drugs and its ingredients.
- It is unknown how many compounded drugs are dispensed in the outpatient setting.

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GAO Report on Payment Practices of Compounded Drugs – October 2014 (Findings & Recommendation)

Medicare Part B payment policy

- Medicare Part B payment policy for compounded drugs does not specify whether payment is available for non-FDA-approved bulk drug substances.
- Medicare Part B claims contractors do not collect information on FDA-approval status of ingredients.
- Because Medicare Part B payment policy is unclear on whether payment is available for non-FDA-approved ingredients and contractors do not collect FDA-approval information, CMS may have paid for compounded drugs inconsistently with its payment policy.

GAO's recommendation

- ❑ CMS should clarify its Medicare Part B payment policy to clearly allow or restrict payment for non-FDA-approved bulk drug substances.

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Federal Regulations

July 2016

- FDA issued guidance document of its intent to restrict the compounding of drugs that are essentially copies of commercially available or approved drugs.
- States are the principal regulators of compounding pharmacies.

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Federal Regulations

- A compounding pharmacy must register under either a 503A or 503B federal registration. 503B registration defines a compounding pharmacy as an outsourcing facility, and outsourcing facilities are highly regulated compared to a 503A federal registration.
- 503B registration defines an outsourcing facility as (i) a facility that is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of the outsourcing section.

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Federal Regulations

- Entities that register as outsourcing facilities must pay a registration fee, but are not required to be a licensed pharmacy and may or may not obtain prescriptions for identified individual patients.
- Further, outsourcing facilities are subject to current good manufacturing practice requirements ("CGMP"), and the facility must be inspected by the FDA on a risk-based schedule.
- Distinct from compounding pharmacies registered under 503A, outsourcing facilities are not required to obtain prescriptions for identified individual patients, and they are not subject to the interstate distribution restrictions in section 503A.
- However, outsourcing facilities must be compounded in accordance with CGMP requirements, labeled appropriately, subject to adverse event reporting, and otherwise compounded in accordance with the conditions of a 503B registration.

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Federal Regulations

- To qualify for 503A registration, the compounding must be performed by a licensed pharmacist or physician and generally must be done pursuant to an individualized patient prescription written by a licensed practitioner who is authorized to prescribe drugs under applicable state law.
- The prescription requirement of 503A generally requires drugs to be compounded after the receipt of a valid prescription order, which includes the patient name.
- However, under section 503A pharmacists may conduct "anticipatory compounding" which allows compounding before the receipt of a valid prescription order, but only if the compounding meets certain requirements.
- This anticipatory compounding may only be done in "limited quantities" and only if the facility has a history of receiving valid prescription orders for the drug product within an established relationship between the compounding pharmacist/physician and the patient or the prescriber.

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Federal Regulations

- Pharmacies should only conduct "anticipatory compounding" for products they expect to receive a prescription order for based on the history of receiving that prescription order on a routine basis.
- Further, compounding in limited quantities may occur prior to receiving a prescription for an identified individual patient, but 503A does not provide for *distributing* a compounded drug product before receiving a valid prescription order for an identified individual patient.
- Therefore, although the anticipatory compounding may take place prior to receive the prescription, the product cannot leave the facility before receiving a valid prescription order for an identified patient.

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Federal Regulations

- The FDA has provided guidance defining what it considers to be "limited quantities" under anticipatory compounding rules. Under this guidance, the FDA will not consider a compounder to have exceeded the limited quantity condition under 503A registration if:
- The compounder holds for distribution no more than a 30-day supply of a particular compounded drug product (i.e. units of a compounded drug product that the compounder believes it will distribute over a 30-day period) to fill a valid prescription it has not yet received; and
- The amount of the supply is based on the number of valid prescriptions that the compounder has received for identified individual patients in a 30-day period over the past year that the compounder selected.

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Federal Regulations

- To ensure compliance with the above 503A registration, a pharmacy shall only compound "limited quantities" of a drug before receiving a valid prescription order.
- The pharmacy should only compound these "limited quantities" if the physician or pharmacist has a history of receiving valid prescription orders for that individual patient.
- The "limited quantities" of the sterile product, pre-compounded prior to receiving a valid prescription, w*ill not exceed a thirty (30) day supply at any time*.
- The pharmacy should keep detailed records to demonstrate compliance with the prescription requirement.
- These records should include, but not be limited to, valid prescription orders, the quantity of a particular drug compounded in advance, and the basis for that quantity.

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