Regulatory and Reimbursement Mega Session

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AGENDA

- Federal
  - New PINs
  - New HRSA Accounting and Budgeting PIN
  - New FQHC Medicare PPS
  - OMB "Super Circular"
  - HRSA Site Visits
  - The Latest on Agency Enforcement Activities
- New York State
  - Lawsuit Update
  - School-Based Health Centers and managed care
  - Executive Order #38
  - Nonprofit Revitalization Act of 2013
  - Proposed Regulations - Integration of Physical Health and Behavioral Health

Federal Updates

PIN 2014-01: GOVERNANCE

- **Policy Information Notice (PIN) #2014-01:** *Health Center Program Governance* (effective upon publication on January 27, 2014)
  - Primary HRSA policy statement regarding health center governance requirements
- Key clarifications on governance requirements:
  - For board composition, a "patient" must be: currently registered, accessed care in past 2 years, and received at least one in-scope service that generated a health center visit
  - Non-consumer members do not have to have specific expertise
  - No more waivers of the monthly meeting requirement
  - Required bylaws provisions, board involvement in certain activities
  - Incorporates affiliation policies from PINs #97-27 and #98-24 regarding third-party involvement in Board composition and decision-making

PIN 2014-02: SLIDING FEE DISCOUNT PROGRAM

- **Policy Information Notice (PIN) #2014-02:** *Sliding Fee Discount and Related Billing and Collections Program Requirements* (effective upon publication, September 22, 2014)
  - Applies to Section 330 grantees and look-alikes
  - Primary resource for HRSA's sliding fee discount program (SFDP) policy, superseding all prior guidance
    - HRSA also issued a document with responses to comments on the draft PIN "Clarification of Sliding Fee Discount Program Requirements"
  - Main goal is to minimize financial barriers to care (*i.e.*, neither the fees nor the operational procedures should present obstacles)
  - Full board must approve and periodically review **all** SFDP policies, not just the sliding fee discount schedule, including:
    - Eligibility and verification requirements
    - Sliding fee discount schedule
    - Billing and collection policies;
    - Policies to waive/reduce fees to ensure access
  - SFDP applies to all services furnished within the health center's scope of project for which a charge has been established, (required or additional) regardless of the type of service or mode of

PIN 2014-02 CONT'D:
SLIDING FEE DISCOUNT SCHEDULE

- Income and family size are the sole factors in determining eligibility (Board has discretion to define "family" and "income")
  - Additional factors cannot be considered *(e.g.*, population type and insurance status).
  - Health centers cannot require patients to apply and be turned down for insurance prior to accessing the SFDS, or provide a "blanket" waiver of fees for all individuals in a special population.
  - SFDS must be applied uniformly to all patients who qualify.
- Must include at least three graduated "pay classes" between 101% - 200% of the Federal Poverty Guidelines (FPG) (may be a percentage or a flat fee)
- May charge a nominal fee (rather than offer a full discount) to individuals and families whose annual incomes are at or below 100% of FPG (*i.e.*, a fixed flat rate fee; it is <u>not</u> a threshold for receiving care)
- If a patient chooses not to provide the required eligibility verification information, health centers may deem the patient ineligible and charge them full fee (provided this policy is applied uniformly).
- Health centers receiving non-330 funding sources that provide for discounts above 200% (such as Ryan White funds) may reduce such patients' payments accordingly by allocating all or some of the charge to such other source

PIN 2014-02 CONT'D:
REFERRALS, COST-SHARING, AND SUPPLIES

- **Referral Arrangements** (*i.e.*, Column III on Form 5A) must include discount schedules that conform to the structural requirements outlined in the PIN and nominal charges that meet the definition in the PIN.
- **Cost-Sharing:** If a patient's cost-sharing amount is more than the amount (s)he would have been charged as an uninsured patient on the SFDS, the health center must reduce the cost-sharing amount to the applicable SFDS level
  - Health centers may provide further discounts in their discretion.
- **Supplies & Equipment:** treatment-related supplies and equipment that are charged separate from the actual service (such as dentures, crowns, eyeglasses, prescription drugs, etc.) may be discounted based on a structure that is different from the SFDS.
  - Can set prices to recoup costs, even if greater than the "regular" discount rate, provided that patient access is supported and the center has provisions in place to waive or reduce fess as necessary to ensure such access.

PIN 2014-02 CONT'D:
BILLING AND COLLECTIONS POLICIES

- Health centers must establish policies and procedures that identify circumstances under which fees will be reduced or waived to ensure access.
- Health centers may offer prompt payment or cash payment discounts as payment incentives, provided that these discounts are available to all patients regardless of income level or SFDS pay class, and are applied uniformly.
- Health centers may establish policies to discharge patients for refusal to pay amounts owed, provided that discharge is the "last resort" after reasonable collection efforts are made. At a minimum, the policy should define "refusal to pay" and identify how determinations will be made and what collection actions will be taken prior to discharge.

NEW OPERATIONAL SITE VISIT (OSV) GUIDE

- New Operational Site Visit Guide released January 2014
  - Reviewers started using the new OSV Guide in April 2014
- Maintains objective 19 program requirements
- Removes subjective performance improvement sections
- Describes uniform site visit format and outcomes
  - Reviewers must produce a standardized site visit report
  - On-site reviewers work with project officer before, during and after review
- Designed to ensure OSV review is based on objective program requirements and not subjective performance improvement recommendations

UPDATED FTCA MANUAL (JULY 21, 2014)

- HRSA issued new *Federal Tort Claims Act: Health Center Policy Manual*
  - Reflects the final rule published in a Federal Register Notice from September 23, 2013 that expanded and clarified FTCA coverage for certain services provided to non-health center patients under certain circumstances:
    - The services furnished by the health center provider(s) to the non-health center patient are within the health center's scope of project
    - The health center provider is asked to temporarily assist in an individual emergency situation at or near the provider's location
    - The provision of individual emergency treatment, when the provider is already providing or undertaking to provide covered services, must be a condition of employment at the health center (*e.g.*, documented in a job description or employee manual)
  - Clarifies that FTCA coverage is available when health center providers conduct or participate in health fairs and immunization campaigns on behalf of the health center (previously coverage was only available when health center directly conducted such activities)
  - Covered immunization campaigns include immunizations provided to children, adolescents, and adults

PIN 2013-01: BUDGETING AND ACCOUNTING

- **PIN 2013-01:** *Health Center Budgeting and Accounting Requirements (issued March 18, 2014)*
  - Recodifies the "total budget concept" applicable to in-scope activities for §330 funded health centers and look-alikes
    - Since look likes do not receive federal funds, it applies "to the extent they describe the appropriate use of non-grant funds"
  - Modifies certain accounting principles related to federal vs. non-federal funds
  - Reiterates the governance responsibility to ensure funds are tracked and spent appropriately
  - If a health center has a subrecipient, applies equally to the subrecipient as to the primary grantee
  - Applies to in-scope activities only

PIN 2013-01: BUDGETING AND ACCOUNTING

The "new" PIN impacts numerous aspects of a health center's financial management system

- Budget preparation
- Cost allocations
  - Time and effort reporting
- General ledger systems and separate accounting of Section 330 grant funds
  - Allowable costs (OMB Circular A-122)
  - Procurement standards
  - Property management standards
- Monitoring of Federal grant budget
- Drawdowns of Federal grant funds
- Federal Financial Report (FFR) preparation

PIN 2013-01: BUDGETING AND ACCOUNTING

So, what should we do?

Develop appropriate allocation methodologies:

- Section 330 Scope of Project
  - Section 330 Grant Funds
  - Non-grant funds
    i. State and local government funding (grants/contracts)
    ii. Other (private/corporate foundations)
    iii. Other Federal grants that are part of the Section 330 scope of project
    iv. Patient services revenue
- Non-Federal Section 330 scope of project activities ("Other Lines of Business")
  - Allocate all direct and indirect costs
  - These programs should be self-sustaining

PIN 2013-01: BUDGETING AND ACCOUNTING

So, what should we do?

For costs allocated to the Section 330 scope of project, develop an allocation plan for allocating costs to the Section 330 Federal grant:

Step 1 - Start with your total costs and then allocate to appropriate revenue sources

Step 2 - Remove unallowable costs (to be covered by non-grant funds) including salaries over the Federal salary cap

Step 3 - Remove costs that are restricted and covered by non-grant funds

Step 4 - Following steps 1-3, the total costs remaining will be a pool of dollars to be allocated between Section 330 grant funds and non-grant funds; within this pool:

- 1st - Allocate those cost that may be 100% covered by Section 330 funds (e.g., O&E, Expanded Services or appropriate enabling services)
- 2nd - The balance can then be allocated to the Section 330 grant based on a reasonable and justifiable basis and consistent with HHS policies and other federal requirements

PIN 2013-01: BUDGETING AND ACCOUNTING

So, what should we do?

Decide on an allocation method for apportioning shared costs between Section 330 grant and non-grant funds:

- Self-pay visits as a percentage of total visits
  - Comment: Section 330 grant pays for more than just services to self-pay patients
- Section 330 grant revenue as a percentage of total revenue
  - Factor in "order of spending" concept
- Allocate entire Section 330 grant to one specific item of expense within the Federal scope of project utilizing the "total budget concept"
  - Comment: FQHC Medicare and Medicaid cost based rates are paying, indirectly, for all types of expenses
- Allocate only to personnel costs
  - Support by time-and-effort reporting

Whatever methodology selected must be reasonable and justifiable!

PIN 2013-01: BUDGETING AND ACCOUNTING

So, what should we do?

Develop monthly budget versus actual monitoring procedures:

- Health Center Program grantees must track their Section 330 grant spending to ensure that:
- Expenditures are consistent with the HRSA approved budget and utilized for allowable costs
- As necessary, HRSA approvals are requested and received consistent with 45 CFR 74.25 (applies to re-budgeting among federal object budget class categories)

HRSA Operational Site Visit Guide:

Program Requirement No. 14 states – "Are there budgetary controls in effect (e.g., comparison of budget with actual expenditures on a monthly basis) to preclude drawing down Federal funds in excess of: (1) Total funds authorized on the Notice of Award? and (2) Total funds available for any cost category, if restricted, on the Notice of Award?"

PIN 2013-01: BUDGETING AND ACCOUNTING

So, what should we do?

Develop Federal grant drawdown procedures that are consistent with the various requirements of the "new" PIN:

- Per OMB Circular A-110 cash management principles, drawdowns must be supported by actual expenses that have been disbursed as reasonably soon as possible (within 3 days)
  - Advances for current month's expenditures
  - Reimbursement method for prior month's expenditures?
- The expenses that the Section 330 grant drawdown is being used to cover need to be tracked separately and be consistent with the accounting of Section 330 grant funds in the accounting records
- Consider the impact of the "order of spending" in the determination of Excess Program Income versus Unobligated Balance of Federal Funds

PIN 2013-01: BUDGETING AND ACCOUNTING

So, what should we do?

Develop procedures to ensure the annual FFR for grant reporting is consistent with the requirements of the "new" PIN:

- Tracking of specific expenses relative to the Section 330 Federal grant conflicts with the long-standing "order of spending" concept relative to the earning of the Section 330 Federal grant
- The "new" PIN reiterates the concept of Excess Program Income
  - "The proposed amount of Federal Section 330 grant funding to support the scope of project may not exceed the amount by which the projected cost of operations exceeds the projected non-grant revenue sources"
- In preparing the annual FFR, health centers need to consider both the specific expenses charged to the Section 330 Federal grant as well as the "order of

NEW FQHC MEDICARE PPS SYSTEM

- Affordable Care Act required the development and implementation of a Medicare Prospective Payment System (PPS) for FQHCs to account for:
  - Type
  - Intensity
  - Duration

  } of services furnished by FQHCs

- CMS finalized the Medicare PPS April 29, 2013, with an implementation date beginning with cost reporting periods beginning on or after October 1, 2014
- Payment methodology is based on 80% (preventive services 100%) of:

*the **LESSER** of actual charges **OR** the "new" FQHC Medicare PPS rate*

NEW FQHC MEDICARE PPS SYSTEM

- Base payment for $158.85 from October 1 through December 31, 2015
- PPS base rate will be updated annually
  - 2016 - by the Medicare Economic Index (MEI)
  - 2017 - by the MEI or a FQHC market basket
- FQHCs will transition to the FQHC PPS on the first day of their cost reporting period that begins on or after October 1, 2014
- 34.16% increase in the PPS rate (and no coinsurance) for:
  - New patients
  - Patients receiving an Initial Preventive Physical Examination (IPPE)
  - Patients receiving an Annual Wellness Visit (AWV) (initial or subsequent)

NEW FQHC MEDICARE PPS SYSTEM

The FQHC Medicare PPS rates will be calculated as follows:

- FACE to FACE Encounter :

  Base payment rate ($158.85) x FQHC **GAF** = PPS rate

- IPPE:

  Base payment rate ($158.85) x FQHC **GAF** x 1.3416 = PPS rate

Impact:

- The GAF for Onondaga County ("Rest of New York") 2014 = 0.966
- Therefore, the base rate for Onondaga will be $158.85 x 0.966 = $153.45
  - Current rate = $129.02 (urban)
  - At 80%: $122.76 PPS vs. $103.22 current (urban) **+19%**
  - PPS preventive (IPPE) = $153.45 x 1.3416 = **$205.87** **+60%**

NEW FQHC MEDICARE PPS SYSTEM

Other Highlights:

- What is a "new patient"
  - A "new" patient is someone who has not received any professional medical or mental health services from any site or from any practitioner within the FQHC organization within the past 3 years from the date of service
- FQHCs can bill for more than one visit per day for the following circumstances:
  - Subsequent illness or injury
  - Mental health visit occurring on the same day as another billable visit
- Co-insurance
  - 20% of the lesser of the actual charge or the PPS rate
  - No coinsurance charged for preventive services for which the coinsurance is waived

NEW FQHC MEDICARE PPS SYSTEM

New Codes for Bundled Services:

- G0466 - FQHC visit, new patient
- G0467 - FQHC visit, established patient
- G0468 - FQHC visit, IPPE or AWV
- G0469 - FQHC visit, mental health, new patient
- G0470 - FQHC visit, mental health established patient

Updated Billing Protocols:

One of the above codes must be reported on claims, when applicable, with an associated charge amount reflective of typical services provided during these visits type

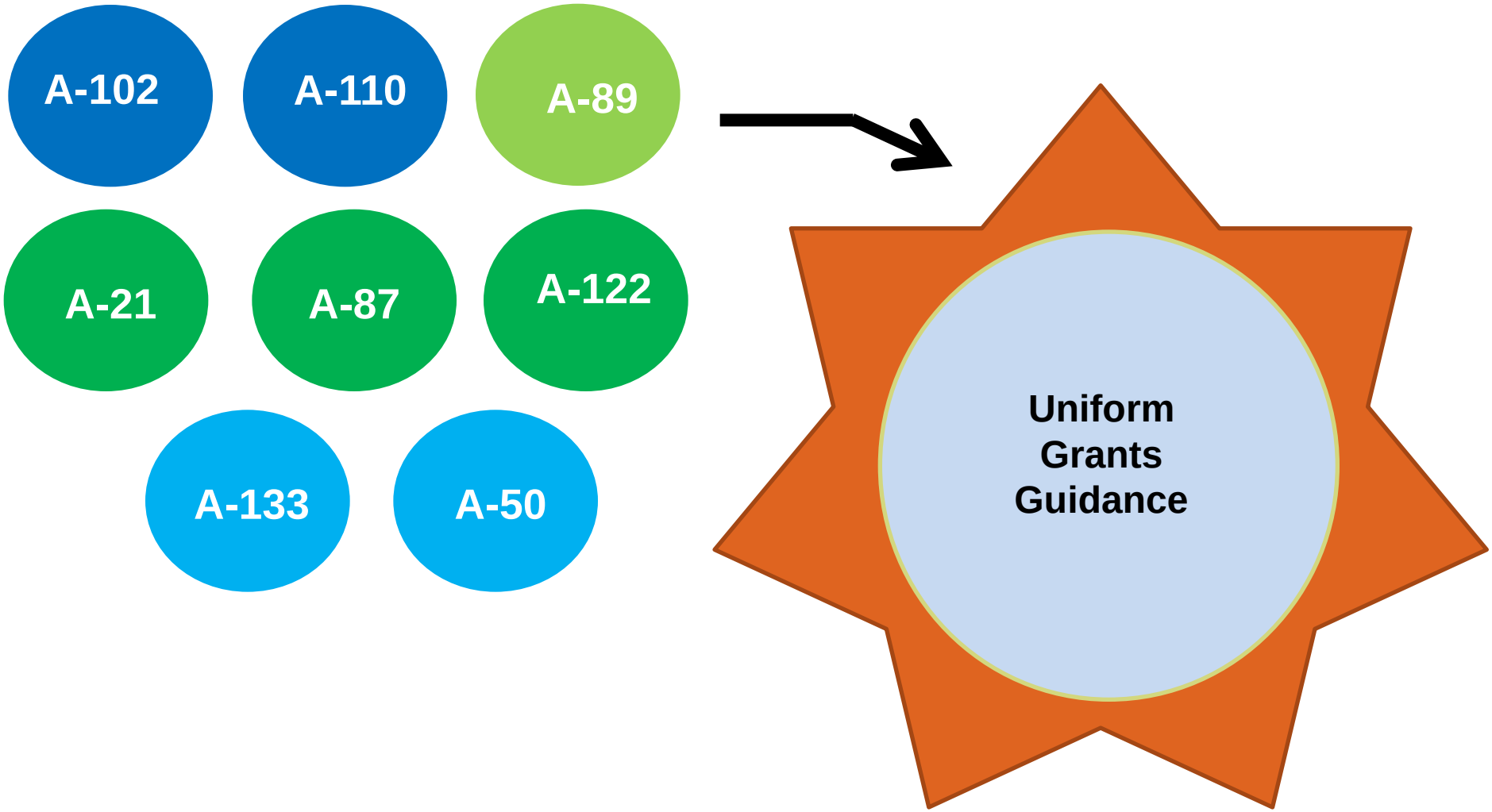
AND

ALL HCPCS codes for services that occurred on the same day

NEW FQHC MEDICARE PPS SYSTEM

- FQHCs that have a written contract with a Medicare Advantage (MA) organization are paid by the MA organization at the rate that is specified in their contract
- If the contracted rate is less than the Medicare PPS rate, Medicare will pay the FQHC the difference, less any cost sharing amounts owed by the beneficiary
  - Applications to establish the average payment amount per visit for each MA organization will continue to be required
- The PPS rate is subject to the FQHC GAF, and may also be adjusted for a new patient visit or if a IPPE or AWV is furnished
- The supplemental payment is only paid if the contracted rate is less than the fully adjusted PPS rate

THE OMB "SUPERCIRCULAR"



THE GOAL IS UNIFORMITY

- New 2 CFR part 200, other circulars will be removed from CFR
  - Same set of rules apply to all Non-Federal Entities (mostly)
  - Consistent terminology
  - Standard grant award documents
  - Some standardization of grant award competition requirements
  - Flow-down of requirements to subrecipient relationships
- Changes to procurement rules
  - Grantees must maintain written standards of conduct covering conflicts of interest and governing the performance of employees engaged in the selection, award and administration of contracts (2 CFR§200.318(c)(2))
  - Sole Source can only be used in certain situations (2 CFR §200.320)
  - Criteria updated for the Simplified Acquisition Threshold (2 CFR § 200.201(b))
  - Micro-Purchase Threshold (below $3,000 or $2,000 in case of some acquisitions for construction) (2 CFR §200.320)

THE SUPERCIRCULAR: TIME & EFFORT REPORTING

- **Overview**
  - More flexibility; less variation between rules applicable to nonprofits and other grantees
  - New rules emphasize overall internal controls, rather than specific required procedures (*e.g.*, budget estimates are useable on an interim basis as long as there is a review process)
  - Overall principle is documentation needs to "accurately reflect the work performed"
- **Documentation Standards (2 C.F.R. §200.430(i)(1))**
  - Personal Activity Reports are no longer the default rule (but government could choose to require them if a grantee does not meet the standards laid out in the Supercircular)
  - No rigid rules as to type of records required
  - Charges for salaries and wages of nonexempt employees must be supported by records indicating hours worked **(no change)**
  - May reflect categories of activities expressed as a

THE SUPERCIRCULAR: OTHER MAJOR CHANGES

- Strong encouragement to use Indirect Cost Rate Agreements (ICRA)
  - Indirect cost rate: specific % applied to a base (*e.g.*, Direct Salaries, Modified Total Direct Costs or Useable Sq. Ft.)
  - If a grantee has a **negotiated indirect cost rate**, all Federal agencies must accept it unless there is a statutory, regulatory, or otherwise approved reason for deviation.
    - Pass through entities also have to recognize their subrecipients' negotiated ICRA between the sub and the feds (if one exists)
  - Minimum flat rate for entities (**10% of modified direct costs**) that have not previously had a negotiated rate before, may be used indefinitely
- Subrecipient vs. Contractor
  - Distinguishes between Subrecipient (2 CFR 200.93) and Contractor (2 CFR 200.22, previously known as "vendors") based on the nature and purpose of the funds
  - Impacts procurement requirements, reporting obligations,

AGENCY ENFORCEMENT UPDATES

- Increase in audits and reviews by various agencies:
  - OIG
    - Grants Management Audits
  - HRSA
    - Operational Site Visits
    - Federal Tort Claims Act Site Visits
    - 340B Drug Pricing Program Audits
    - National Health Service Corps Site Visits
  - Office for Civil Rights
    - HIPAA Audits

OIG ENFORCEMENT: RETURN ON INVESTMENT

	FY 2011	FY 2012	FY 2013
Individuals and entities excluded from Federal health care programs	2,662	3,131	3,214
Total health care fraud judgments and settlements	$2.4 billion	$6.9 billion	$5.8 billion
Return on investment from various HCFAC activities	**$1.5 to $1**	**$7.9 to $1**	**$8 to $1**

S[illegible]14, FY 2013)

OIG GRANTS MANAGEMENT AUDITS

- In random audits, OIG found that some health centers lacked written policies and procedures, and appropriate documentation, primarily related to grants management:
  - Procurement
  - Accounting for property leased or acquired utilizing Federal grant funds
  - Federal grant reporting
  - Accounting system
    - Segregation of duties
  - Well-publicized whistleblower policy and procedures

OPERATIONAL SITE VISITS

- Nearly 400 OSVs conducted in CY 2013
- For CY 2014 - approximately 700 site visits across all BPHC programs - over 500 of them will be OSVs
- In addition to full OSVs, other site visits may include
  - Targeted program requirement compliance verification
  - Targeted program requirement compliance assessment
  - Program requirement assistance site visit
  - Performance improvement site visit
  - Specialized site visits (case by case issues - financial recovery plans, service area overlap)

SITE VISIT HIGH RISK AREAS

Services

- #16: Scope of Project
- #2: Required & Additional Services

Management and Finance

- #7: Sliding Fee Discounts
- #10 & #11: Collaborations & Affiliations

Governance - to be discussed in another session

- # 17: Board Authority
- #18: Board Composition
- #19: Conflict of Interest Policy

HOT ISSUES IN OPERATIONAL SITE VISITS

- Scope of Project
  - Maintain accurate and up to date Scope of Project
  - Ensure scope changes are made on a timely basis
  - Segregate out-of-scope activities
- Required and Additional Services
  - Ensure mix and level of services is consistent with needs assessment
  - Determine most effective mode of delivery for each in-scope service
  - Ensure hospitalization and other referral arrangements are formalized and compliant
  - Ensuring that formal written contracts / referrals include all required provisions
  - Ensuring that after-hours coverage and hospitalization arrangements comply with Site Visit Guide

HOT ISSUES IN OPERATIONAL SITE VISITS

- Schedule of Charges
  - Consistent with locally prevailing charges
  - Designed to cover the health center's costs
- Schedule of Discounts
  - No discounts for patients with annual income above 200% FPL
  - No more than a nominal fee for patients at or below 100% FPL
  - Ensure discounts offered by in-scope referral providers or pay the difference

HOT ISSUES IN OPERATIONAL SITE VISITS

- Collaborations & Affiliations
  - Structuring affiliations / collaborations in compliance with all Section 330-related requirements (including service requirements and affiliation policies) and, as appropriate, procurement rules
    - PINs # 1997-27 and #1998-24 address Affiliation Agreements
  - Addressing concerns regarding potential service area overlap with other FQHCs

NOTE: beyond OSVs, critical to address external pressures and "politics"

OPERATIONAL SITE VISITS

Management and Finance:

- 2014 Updates to the HRSA Operational Site Visit Guide:
  - Program Requirement No. 12 states - "Specifically, does the health center's accounting system provide for: (1) separate identification of Federal and non-Federal transactions? and (2) a chart of accounts that reflects the general ledger accounts?"
  - Program Requirement No. 14 states - "Are there budgetary controls in effect (e.g., comparison of budget with actual expenditures on a monthly basis) to preclude drawing down Federal funds in excess of: (1) Total funds authorized on the Notice of Award? and (2) Total funds available for any cost category, if restricted, on the Notice of Award?"

OPERATIONAL SITE VISITS

Management and Finance:

- Common Findings and Observations -
  - Sliding fee scale practices consistent with the new PIN
  - Schedule charges should be cost-related and take into account prevailing rates in the community
  - Policies and procedures to be approved by the Board of Directors
  - Accounting policies and procedures should reflect
    - New PINs
    - Old regulations - 45 CFR Part 74 and A-122
  - Patient revenue recognition procedures and A/R reconciliation
  - Financial statements should have budget versus

FEDERAL TORT CLAIMS ACT SITE VISITS

- HRSA may conduct a FTCA site visit during the deeming application process and/or as part oversight responsibilities to ensure appropriate implementation of:
  - Risk Management (including HIPAA, medical records, risk management training, documentation)
  - QI/QA policies and procedures (including QI/QA plan, minutes from QI/QA committee and board meetings, clinical practice protocols)
  - Credentialing & Privileging policies and procedures (including peer review, and credentialing/privileging files and spreadsheet)
  - Professional Liability (including claims tracking and management system)
  - Other related FTCA requirements (including referral tracking, diagnostic tracking and hospitalization policies; triage policies; walk-in and no show policies)

FEDERAL TORT CLAIMS ACT SITE VISITS

- Factors that may prompt a FTCA site visit include, but are not limited to:
  - Submission of an initial FTCA deeming application
  - Documentation submitted with application that indicates non-compliance with requirements
  - Need to conduct follow-up based on prior site visit findings or other identified issues
  - History of repeated conditions (or current conditions) related to FTCA-related requirements placed on the grant, as documented on the NoA
  - History of medical malpractice claims

HOT ISSUES IN FTCA SITE VISITS

- Site visit team priorities:
  - Appropriate policies and procedures to reduce risk of malpractice and lawsuits arising out of health/health-related functions
  - Verification of professional credentials, references, claims history, fitness, professional review organization findings, and licensure status of physicians and other licensed or certified health care practitioners
  - If a history of claims exist, documentation of full cooperation with the Attorney General in defending against any such claims and pursuit of any necessary corrective steps to assure against such claims in the future
  - According to HRSA, site visit results <u>will not</u> affect current deeming status; however, be sure to respond to findings prior to next deeming cycle

340B AUDITS

- In response to GAO report and Congressional interest, Office of Pharmacy Affairs has begun:
  - Annual re-certification of all covered entities (CEs), including contract pharmacy arrangements
  - OPA anticipates conducting between 200-300 audits in FY 2015 - targeted and random
    - Review of relevant policies and procedures
    - Verification of CE eligibility
    - Verification of internal controls to prevent diversion and duplicate discounts
    - Medicaid exclusion file listing
    - Contract pharmacy compliance
    - Testing 340B transaction records on sample basis
  - Note: Significant uptick in 340B purchases and/or large contract pharmacy networks attract audits

340B AUDITS

- Manufacturer Audits
  - Only one audit of a covered entity will be permitted at any one time. When HRSA has received a request from a manufacturer to conduct an audit, HRSA will determine whether the audit should be performed by the Government or the manufacturer.
  - Audit must be conducted by independent auditor
  - Oral briefing at end of audit and written report (shared with OIG)
  - Covered entity has 30 days to respond and can challenge findings

HOT ISSUES IN 340B AUDITS

- Diversion
  - Contract pharmacy dispenses 340B drugs to non-patients
  - Prescription written by ineligible provider
  - No patient record documenting prescription
  - Delivery site not registered on OPA database
- Contract Pharmacies
  - No written contract
  - Actual delivery sites do not match OPA database

HOT ISSUES IN 340B AUDITS

- Duplicate Discounts
  - Inaccurate record on OPA Medicaid Exclusion File
    - Billing Medicaid contrary to data on file
    - No NPI or Medicaid billing number registered
  - Using contract pharmacy to dispense to Medicaid fee-for service beneficiaries without method to prevent duplicate discounts
- Administrative
  - Registration of new health center sites with OPA
  - Wrong authorizing official or contact person
  - No, or inadequate, written policies and procedures for 340B program

POTENTIAL SANCTIONS

- HRSA Sanctions
  - Corrective action - prospective
  - After notice and hearing:
    - Repay amount of discount to manufacturer
    - Pay interest on discount for "knowing and intentional" diversion
    - Removal from 340B Program and disqualification for a "reasonable" period of time if violation was "systematic and egregious"
- Collateral Sanctions
  - False Claims
  - Related penalties

NATIONAL HEALTH SERVICE CORPS

- All NHSC-approved sites should expect periodic site visits to identify at-risk sites, provide opportunities to address technical assistance needs, and increase NHSC program compliance
- Standard audit tool that focuses on the NHSC Site agreement, which addresses eligibility and qualification requirements, including but not limited to:
  - Non-discrimination due to inability to pay, payor source, insurance status, race, ethnicity, national origin, disability, religion, age, gender, sexual orientation
  - Sliding Fee Schedule
  - Credentialing
  - Provision of comprehensive care
  - Clinical recruitment and retention plan
  - Sound financial management policies
  - Other issues: NHSC providers' hours of service and location of service

HIPAA ENFORCEMENT ACTIVITY

- HIPAA Final Rule Changes
  - Business Associate definition expanded
  - Notice of Privacy Practices requirements updated
  - Breach definitions changed and risk assessment requirement added
- Compliance issues investigated most by the Office for Civil Rights, DHHS:
  - Impermissible uses and disclosures of PHI
  - Lack of safeguards of PHI
  - Lack of patient access to their PHI
  - Uses or disclosures of more than the minimum necessary PHI
  - Lack of administrative safeguards of electronic PHI

2014 ENFORCEMENT HIGHLIGHTS

- Skagit County, Washington **($215,000)**: First settlement with a county government
  - Exposure of ePHI for 1,581 individuals when files were inadvertently moved to a publicly accessible server maintained by the county
- Concentra Health Services **($1.7 million)**: Unencrypted laptop stolen
  - Failure to remedy identified lack of encryption; lack of adequate risk management strategies
- QCA Health Plan, Inc. of Arkansas **($250,000)**: unencrypted laptop with PHI of 148 individuals stolen from employee car
- New York and Presbyterian Hospital **($3.3 million)**: disclosed 6,800 patients' ePHI to Internet search engines when a computer server with access to hospital systems was errantly reconfigured
- Columbia University **($1.5 million)**: Failed to conduct adequate risk analysis prior to breach and failure to monitor systems linked to ePHI at New York and Presbyterian Hospital
- Parkview Health System, Inc. **($800,000)**: left boxes of medical records unattended in a driveway

ON THE HORIZON…

- The HIPAA Audits Are Coming!
  - Creation of pool of covered entities (CEs) eligible for audit is complete
  - Screening "pre-survey" sent to CEs in summer 2014 to confirm size, type, etc.
  - Selected CEs will receive notification and data requests in fall 2014
    - Will include business associates
  - Both desk and on-site audits
  - Updated protocol will be available on website
- Use OCR's new Security Risk Assessment Tool: http://www.healthit.gov/providers-professionals/security-risk-assessment-tool

Source: OCR Presentation at HCCA

WHAT WILL THE AUDITS LOOK FOR?

<table>
<tr><th colspan="2">2014</th><th>2015</th><th>2016</th></tr>
<tr><td>Covered Entities (about 350)</td><td>Business Associates (about 50)</td><td>Computing device and storage media security controls</td><td>Encryption and decryption</td></tr>
<tr><td>Security rule's requirement of risk analysis and risk management</td><td>Security risk analysis and risk management</td><td>Transmission security</td><td>Facility and physical access control</td></tr>
<tr><td>Breach notification rule, including content and timeliness of notifications</td><td rowspan="2">Breach reporting to covered entities</td><td rowspan="2">Privacy rule safeguards, including workforce training, policies, and procedures.</td><td rowspan="2">Other areas of high-risk as identified by 2014 audits, breach reports, and complaints.</td></tr>
<tr><td>Privacy rule provisions requiring giving patients a notice of privacy practices & providing access to protected health information</td></tr>
</table>

New York State Updates

LAWSUIT UPDATE

- On October 7, 2014, the U.S. Court of Appeals issued its decision on the Medicaid PPS payment methodology lawsuit
- The Court declared lawful:
  - Current Medicaid PPS rate-setting system including the use of peer group ceilings
  - Current payment rates for off-site and group counseling services
  - Use of a prospective system for calculating the Medicaid Managed Care Shortfall Payment ("wraparound")
  - Updated dental policy (cleanings and exams performed in one visits unless documented otherwise)

LAWSUIT UPDATE

- The Court declared unlawful:
  - Policy of denying any payment obligation to the FQHCs for Medicaid services that they provide for which the MCO failed to pay
  - Policy of denying any payment obligation to FQHCs for providing out of network services
- Sent back to the District Court:
  - While NYS may be permitted to calculate its supplemental payment obligation using a prospective payment rate, its current methodology for doing so is flawed as it incorporates the state's unlawful paid claim policy. The Court sent this issue back to the district court to ensure that the state's payment methodology achieves what the federal Medicaid statute requires: a payment equal to the difference between what the centers actually receive from the MCOs and the total amount the centers are owed under their respective PPS rates

SCHOOL-BASED HEALTH CENTERS

- Services provided at School-Based Health Centers (SBHCs) are currently "carved-out" of the Medicaid managed care program
- SBHC services will be carved-in to the Medicaid managed care program effective July 1, 2015
- SBHCs will continue to receive fee-for-service reimbursement for 2 years after implementation
- DOH has convened a work group to work through the implementation issues

SCHOOL-BASED HEALTH CENTERS

- Discussion Topics/Issues:
  - Ensuring PPS reimbursement during the 2-year transition period
  - Contracting with Medicaid managed care organizations
    - What if the sponsoring provider organization does not have a contract with an MCO? Out-of-network clause for payment?
    - Credentialing requirements? Mid-levels?
    - Prior authorizations/denials
    - Contracting with MCO subcontractors (e.g. dental, behavioral health services)
    - Reimbursement for mobile dental services

NYS FINAL REGULATIONS – EXECUTIVE COMP & ADMIN EXPENSES

- Governor Cuomo's Executive Order #38 set forth requirements for executive compensation paid by, and administrative expenses paid to, Covered Providers receiving State Funds and State-Authorized Payments (SF/SAP)
- Final regulations have been issued, effective for covered reporting periods beginning on or after July 1, 2013
- New York State has established a website containing the preliminary guidance and required reporting for the implementation of Executive Order #38 for all covered providers
  - *LEGAL NOTICE POSTED: Based upon the April 8, 2014 decision in Agencies for Children's Therapy Services, Inc. v. New York State Department of Health, et al. ("ACTS"), covered providers conducting business in Nassau County need not file Executive Order 38 disclosures. For purposes of this notice, "conducting business" means having a place of business within Nassau County, providing program services or administrative services involving the use or receipt of State funds or State-authorized payments within Nassau County, or otherwise conducting business within Nassau County in relation to which executive compensation is paid. Please note that the ACTS decision is under appeal.*

NYS FINAL REGULATIONS – EXECUTIVE COMP & ADMIN EXPENSES

Administrative Expense Limits:

- For Covered Reporting Periods (CRPs) commencing between July 1, 2013 and June 30, 2014 - Unless a waiver is granted, no less than 75% program service expenses (no more than 25% administrative expenses) as a proportion of covered operating expenses can be paid with SF/SAP
- For CRPs commencing between July 1, 2014 and June 30, 2015 - The administrative expense limit reduces to 20%
- For CRPs commencing between July 1, 2015 and thereafter - The administrative expense limit reduces to 15%

NYS FINAL REGULATIONS – EXECUTIVE COMP & ADMIN EXPENSES

Executive Compensation Limits:

- Unless a waiver is granted, a Covered Provider may not use more than $199,000 in SF/SAP to provide Executive Compensation to any Covered Employee during the CRP
- Unless a waiver is granted, a Covered Provider may not provide Executive Compensation in excess of $199,000 during the CRP using any sources of revenue IF either of two (2) situations apply:
  - The Executive Compensation exceeds the 75th percentile of compensation provided to comparable executives; or
  - The Executive Compensation was not reviewed and approved by the Covered Provider's governing body, with certain conditions met
- The limit on Executive Compensation will be reviewed annually to determine whether adjustment is necessary

NYS FINAL REGULATIONS – EXECUTIVE COMP & ADMIN EXPENSES

Reporting:

- A Covered Provider must submit an *EO #38 Disclosure Form* no later than 180 days after the close of the Covered Provider's CRP
  - Final *EO #38 Disclosure Form* has been posted to the EO website
  - Reports will be submitted electronically through the EO website
- If, after a review period of not more than 60 days, a determination is made that the Covered Provider violated any of the limitations, or failed to submit the required or requested information, the Covered Provider may be considered non-compliant

NYS FINAL REGULATIONS – EXECUTIVE COMP & ADMIN EXPENSES

Waivers:

- Waivers must be submitted no later than concurrently with the submission of the Covered Provider's *EO #38 Disclosure Form*
- Covered Providers that anticipate exceeding the Administrative Expenses and/or Executive Compensation limits may apply for a waiver in advance of submission of the *EO #38 Disclosure Form*

Plans of Corrective Action/Penalties:

- If a Covered Provider is found to be out of compliance with the requirements of the regulations, the Covered Provider enters the Plan of Corrective Action/Penalties period
- During this period, the Covered Provider and NYS exchange information with the intent of bringing the Covered Provider into compliance
- If the end result of this period is that the Covered Provider remains out of compliance, sanctions will be imposed on the Covered Provider

PRELIMINARY GUIDANCE AND WEBSITE

- New York State has established a website containing preliminary guidance relative to the implementation of EO #38

http://executiveorder38.ny.gov/

- The website includes the following information:
  - Preliminary Guidance
  - Frequently Asked Questions
  - Recommended Worksheets
  - Waiver Application

NOW WHAT?

Now What?

- Analyze your expected Covered Reporting Period and the one-year immediately preceding to determine -
  - Whether your organization is a Covered Provider
  - The State Funds and State-Authorized Payments received by your organization
  - The possible Covered Executives
- Review the accounting system to ensure it is structured to report on Program Services and Administrative Expenses consistent with EO #38 requirements
- Review the process for approval of Executive Compensation and evaluate it's compliance with EO #38 requirements
- Determine whether waivers may be necessary and consider filing waivers prior to the submission of the EO #38 Disclosure Form

NY NONPROFIT REVITALIZATION ACT

- Reforms the statutory requirements for governance of nonprofit organizations in New York
- Most provisions took effect July 1, 2014
- Many of the requirements are similar to those already imposed on health centers by HRSA:
  - Organizations must have a conflicts of interest policy.
  - No employee may serve as chair of the Board or hold any other title with similar responsibilities (not applicable until January 1, 2016).
  - Boards must oversee financial audits and (larger organizations with over $1 million in annual revenue must follow additional oversight procedures).
- Health centers should review bylaws, conflicts of interest policies, and treatment of related party transactions to ensure full compliance with the updated requirements

NY NONPROFIT REVITALIZATION ACT: CONFLICTS OF INTEREST POLICY

- An organization's Conflict of Interest Policy, at a minimum, must include:
  - (a) a definition of the circumstances that constitute a conflict of interest;
  - (b) procedures for disclosing a conflict of interest to the Board;
  - (c) a requirement that the conflicted person not be present at or participate in Board or committee deliberations or vote on the matter;
  - (d) a prohibition of any attempt by the conflicted person to influence improperly the deliberations or voting on the matter;
  - (e) a requirement that the existence and resolution of the conflict be documented in organization records, including minutes of any meeting where the conflict is discussed or voted on; and
  - (f) procedures for disclosing, addressing and documenting related party transactions.
- Each board member must submit annually to the secretary a signed written statement identifying, to the best of the director's knowledge:
  - (1) any entity of which the director is an officer, director, trustee, member, owner or employee, with which the organization has a relationship and
  - (2) any transaction in which the organization is a participant and in which the director might have a conflicting interest.

NY NONPROFIT REVITALIZATION ACT CONT'D

- Covered organizations must adopt a Whistleblower Policy, which includes:
  - Protection from intimidation, harassment, discrimination, other retaliation, or, if applicable, adverse employment consequences
  - Procedures (including confidentiality provisions) for reporting violations
  - A designated person to administer the policy and report to the Board
- Related Party Transactions
  - Any transaction, agreement or other arrangement involving the organization (or an affiliate) and in which a related party has a financial interest
  - A covered organization may not enter into a related party transaction unless the Board determines that the transaction is fair, reasonable and in the organization's best interest at the time of determination
  - A director, officer or key employee who has an interest in such a transaction must disclose such interest to the Board or an authorized committee
- No person who may benefit from a compensation arrangement may be present at or participate in any Board or committee deliberation or vote concerning that person's compensation (except to present background information or answer prior to the deliberations or voting).

PROPOSED INTEGRATION REGULATIONS

- Proposed regulations to prescribe standards for the integration of physical and behavioral health care services licensed by DOH, OMH and OASAS
- Apply to providers seeking to provide integrated care at a single outpatient site and licensed by at least 2 State agencies
- Proposed regulations are "in addition to" State agency licensing regulations
- Integrated care models
  - Primary care host model
  - Mental health behavioral health care host model
  - Substance abuse disorder behavioral health care host model

PROPOSED INTEGRATION REGULATIONS

- The integrated services provider must be a member of a Health Home
- Standards include:
  - Organization/Administration
  - Treatment Planning
  - Polices and Procedures
  - Integrated Care Services
  - Environment
  - QA, UR and Incident Reporting
  - Staffing
  - Recordkeeping

PROPOSED INTEGRATION REGULATIONS

- CHCANYS comments on proposed regulations:
  - A lead agency should be designated to administer the centralized integrated care application
  - Integrated services licensure should be available to entities beyond those that currently hold dual-licensure
  - Integrated services providers should be permitted to be reimbursed for multiple visits per day
  - The requirement for physical separation of space between types of service providers should be eliminated
  - Other line item edits

QUESTIONS?

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