ABCs of FDRs

Session P3
January 31, 2016
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Presentation Highlights

- About Network Health
- What is an FDR?
- Complying with the Regulations is as easy as A-B-C
  - Attestations and Auditing
  - Business Associate Agreements
  - Contracts

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Network Health - Background

- Founded in 1982, Network Health offers customized commercial and Medicare health plans to employers, individuals and families in more than 16 counties throughout northeast Wisconsin and beyond
- Network Health serves more than 135,000 members, including over 63,000 Medicare beneficiaries
  - More information about Network Health is available at www.networkhealth.com, www.facebook.com/networkhealthwi and at www.twitter.com/networkhealthwi

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What is an FDR?

- First Tier Entity – any party that enters into a written arrangement, acceptable to the Centers for Medicare and Medicaid Services (CMS), with a Medicare Advantage Organization (MAO) or Part D plan sponsor or applicant o provide administrative services or health care services to a Medicare eligible individual under the Medicare Advantage (MA) or Part D program. (42 C.F.R § 423.501)

Fun Fact: This is also an FDR →

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What is an FDR?

- Downstream Entity – any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO or applicant or a Part D plan sponsor or applicant and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. (42 C.F.R. §423.501)

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What is an FDR?

- Related Entity - any entity that is related to an MAO or Part D sponsor by common ownership or control and:
  - Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation;
  - Furnishes services to Medicare enrollees under an oral or written agreement; or
  - Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than $2,500 during a contract period (42 C.F.R. §423.501)

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Plan Sponsor Requirements

- **Must** have a clearly defined process to determine if contracted vendors meet the criteria to be considered an FDR
- **Must** develop procedures to promote and ensure FDRs are in compliance with all applicable regulations
- **Must** have a system in place to monitor FDRs
- **Must** be able to demonstrate monitoring is effective

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Plan Sponsor Requirements

- **Plan sponsors** are ultimately responsible for fulfilling the terms and conditions of its contract with CMS
- When your contracted FDRs are out of compliance, **YOU** are out of compliance

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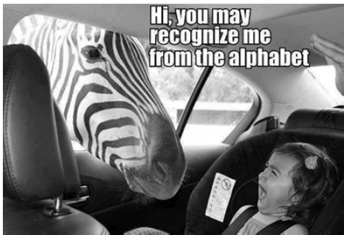
How are we supposed to comply with all of this?!



Trust us, it's not as scary as it seems!

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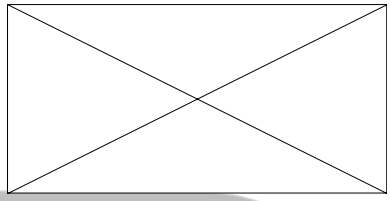
Easy as A-B-C

- The good news is, complying with the regulations is as easy as:
  - A: Attestations and Auditing
  - B: Business Associate Agreements
  - C: Contracts



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C - Contracts

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Contracts

- Have a solid contract process in place
  - If compliance does facilitate/review contracts, ensure compliance is in the loop with new or updated contracts
- Develop a process to determine if vendors are FDRs
  - Network Health utilizes a tool, built from Chapters 9/21 of the Medicare Managed Care Manual, to assist business owners with determining FDR status

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Contracts

CHECK FOR YES, LEAVE BLANK FOR NO/NA

If one or more are checked as YES, the Vendor is automatically considered a Delegated Entity.

- Is/Are the proposed delegated function(s) something Network Health is required to do/provide under our contract with the Centers for Medicare and Medicaid Services (CMS)? ☐
- Will the proposed entity administer any portion of Network Health's Medicare Advantage or QHP benefits? ☐
- Will the proposed entity furnish health care services to Network Health's Medicare Advantage or QHP members? ☐
- Does/Do the proposed function(s) directly impact Network Health's Medicare Advantage or QHP members? ☐

If one or more are checked as YES, contact the Compliance Department for assistance in making the determination (Vendor Might be an FDR). If all are marked NO, the vendor likely is not a Delegated Entity.

- Does the proposed entity have decision making authority in line with Network Health's contract with CMS for our Medicare Advantage or QHP products? ☐
- Does the proposed entity have access to member information or other protected health information (PHI)? ☐
- Will the proposed entity have interaction with Network Health's Medicare Advantage or QHP members either orally or in writing? ☐
- Will the proposed entity lease real property or sell materials to Network Health at a cost of more than $2500 during the contract period? ☐
- Is the proposed entity in a position to commit health care fraud, waste or abuse? ☐

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Contracts

- Develop tools to ensure all required language is included in FDR contracts
  - Network Health created a contract checklist to assist business owners with inserting required language
  - CEO will not sign contracts without completed checklist attached
- Ensure business owners engage compliance during the contracting process
  - Build out valuable monitoring activities for the annual compliance work plan

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Contracts

Note to Checklist User: put page number in blank below____ wherever possible to demonstrate compliance with the requirement.

1. **Sanction Screening** – If the vendor will be working with the Medicare or other governmental program insurance products, contact the compliance department, to request a sanction screen on the vendor prior to signing the contract. Please contact compliance@networkhealth.com to request sanction screening.
   - ☐ The vendor **is not** sanctioned/debarred/excluded (you **may proceed** with contract review)
   - ☐ The vendor **is** sanctioned/debarred/excluded (you **may not continue** with contract review; the Organization will not contract with this vendor)
2. **Sanctions** – If the following are missing, add the terms. If the terms cannot be added during negotiations, please contact the compliance department.
   - ☐ Representation that contractor, any and all employees, subcontractors or any entity the contractor has an ownership interest in, has not been excluded from a federal health care program. *(See sanctions clause attached)*
   - ☐ Agreement to promptly notify the Organization upon receipt of a sanction *(See sanctions clause attached)*
3. **Parties and Purpose** – If the parties and purpose sections do not include the following, add the appropriate terms. If a term cannot be added during negotiations, please contact the Organization's administrative individual responsible for overseeing the subject matter of the contract or General Counsel.
   - ☐ Clear identification of the parties to the contract, using the full and correct legal name

Medicare Advantage Delegated Entity Contract Requirements

*Medicare Vendors Only- If this is **not** a Medicare Advantage contract, skip this section.*

14. **Oversight, Monitoring and Auditing**
    - ☐ Prior to contracting, a detailed oversight, monitoring and auditing plan must be provided to the compliance inbox (compliance@networkhealth.com) for review. All Medicare Advantage contracts must have oversight, monitoring and auditing clause within the agreement. *(See Oversight, Monitoring and Audit clause attached)*
15. **Revocation of Delegation**
    - ☐ All Medicare Advantage contracts must have revocation of delegation within the agreement. *(See Revocation of Delegation clause attached)*
16. **Accountability**
    - ☐ All Medicare Advantage contracts must have accountability within the agreement. *(See Accountability clause attached)*
17. **Sub-Delegation**
    - ☐ All Medicare Advantage contracts must have sub-delegation within the agreement. *(See Sub-Delegation clause attached)*

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Contracts

- Ensure compliance is notified of new or termed contracts
  - Allows you to fulfill requirements within 90 days of contracting and ensure you're not requesting information from termed vendors
- Develop an ongoing process to ensure no potential FDR contracts are missed
  - Set up time to review new contracts monthly or quarterly to catch any vendors that may actually be considered FDRs

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Contracts

- Develop a central location to house FDR information
- At Network Health, a web-based tool is used to track:
  - Primary Contacts at Network Health and at the FDR
  - Initial Contract Dates
  - Completed Attestations (we'll get to that in a bit)
  - Downstream Entities for each First Tier Entity
  - Offshore Entities for each First Tier and Downstream Entity
- This allows us to access the information quickly and easily, as well as pull reports

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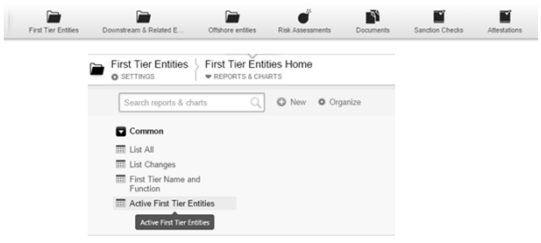
Contracts



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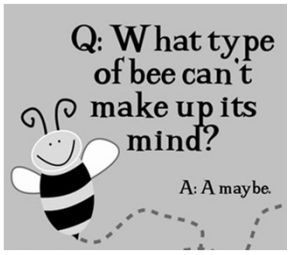
B – Business Associate Agreements



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Business Associate Agreements

- Ensure timelines are within the 'comfort zone'
  - Watch timeframes for vendors to notify your organization of breaches
  - Vendors will often try to negotiate this timeframe
- If you don't have in-house legal, start with your own BAA template
  - This has proven to be a time/cost saver for Network Health

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Business Associate Agreements

- Include the requirement to disclose the use of Offshore Subcontractors
  - Ensure you're reporting these as soon as possible to CMS
- Be aware of the language for the Governing Law State
  - This could lead to issues, should there be a breach or lawsuit
- Ensure BAAs and Contracts do not conflict
  - This is particularly important if separate areas handle BAAs and contract processes

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A – Attestations and Audits

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Attestations and Audits

- Develop and utilize Attestations to evaluate vendor compliance
- Be sure to make updates to the attestations as guidance changes
- Network Health sends out a packet to new vendors within 90 days of contracting which includes
  - Cover letter to introduce attestation process
  - Definitions of important terms
  - Delegated Entity Attestation
  - Offshore Subcontractor Attestation
  - FWA and General Compliance Training attestation
  - Code of Conduct
  - Compliance Program Policy

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Attestations and Audits

- Work closely with your smaller vendors or vendors that may not have much experience with Medicare Advantage products
  - Think about how your organization may be able to minimize the burden by taking on some of the less familiar functions (i.e., sanction screenings)
- Make sure you know who will be completing these (ties back to central storage of FDR information)
- Require general attestations annually
  - Network Health issues bi-annual offshore attestations (you'll be surprised what you learn!)

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Attestations and Audits


IMPORTANT NOTICE – ACTION REQUIRED

Thank you for partnering with Network Health. We appreciate your assistance to help us better serve our members and providers. We're looking forward to working with you.

To ensure our partnership continues to move forward, you'll need to complete and return certain documents. See the Attestation Process Letter and use the checklist below to verify you've reviewed and completed the needed items.

Make sure to return the necessary documents and this checklist no later than _____.

TO RETURN—
- Delegated Entity Attestation
- Attestation of Offshore Subcontractors
- Your Organization's Code of Conduct (see attestation letter for further details)

TO KEEP—
- Attestation Process Letter
- Attestation Definitions
- Code of Conduct
- Compliance Program Overview

If you have questions about any of the materials described above, do not hesitate to contact compliance@networkhealth.com.

Thank you for your cooperation


Date:

Dear Vendor:

Thank you for your continued partnership with Network Health. Attached, you will find attestations required by Network Health in order to demonstrate and document compliance with key program requirements set forth by the Centers for Medicare and Medicaid Services (CMS). We've also included some helpful definitions to reference when completing the attestations.

The first attestation is sent to your organization on an annual basis and consists of elements to determine your compliance with CMS program requirements. If your organization does not meet one or more of the elements listed, you will need to contact the Network Health Medicare compliance department immediately to establish a corrective action plan to fulfill the element(s) as soon as possible.

The second attestation is an offshore subcontractor attestation and is used to evaluate your organization's utilization of offshore resources. This is required on a bi-annual basis.

Delegated Entity Attestation

As a first tier entity of Network Health, _____ hereby attests as follows:

1. _____ is not excluded from participation in Federal health care programs.
   ☐ Yes ☐ No
2. _____ has screened its employees against the Office of Inspector General (OIG) Medicare Exclusions Database (MED) and General Services Administration (GSA) System for Award Management (SAM) database upon their appointment, hire and/or contracting and at least monthly thereafter, as required by the Medicare Advantage and Prescription Drug Programs in the Code of Federal Regulations, 42 CFR 422 and 423.
   ☐ Yes ☐ No
3. _____ has adopted, implemented and distributed a policy and procedure manual as re

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Attestations and Audits

- Develop a risk assessment process
- Be sure to include factors that impact the FDR such as:
  - Findings from CMS program audits
  - Intake Forms (reported compliance issues)
  - Disclosures to CMS
- Network Health audits our two biggest vendors (TPA and PBM) annually
  - They will always be the highest risk due to the functions delegated
  - In previous years, used to strictly conduct these audits onsite, but with WebEx technology, have shifted more to remote audits

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Attestations and Audits

- Ensure each FDR has specific tasks built into the annual compliance work plan
  - Use these to assist with the development of the audit scope
- Adjust the scope for the type of organization you're auditing
  - Focus on risk areas identified through monitoring, program audits, etc
  - For some of Network Health's vendors, the attestation process has been enough to ensure compliant processes are in place

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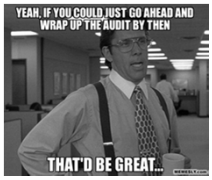
Attestations and Audits

- Ensure all issues identified during audits are closed
  - Follow through on all open items and make sure nothing lingers
- Ensure audits are closed out timely
- Document EVERYTHING
  - Your business owners will thank you for it later!



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Questions

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The ABCs of FDRs (from the Medicaid Side)

Strategic Management
STRATEGIC MANAGEMENT SERVICES, LLC

COOK COUNTY HEALTH & HOSPITALS SYSTEM
CCHHS

Introductions

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Presentation Highlights

- About CCHHS & CountyCare
- FDR on the Medicaid side

It IS as easy as A-B-C!!

- **A**uditing and Monitoring
- **B**uilding the oversight plan
- **C**ontracts

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And…

- Take home ideas and tools for maintaining adequate documentation of your FDR oversight program

- CountyCare is a Managed Care Community Network ("MCCN") plan offered by CCHHS, a healthcare system, pursuant to a contract with the Illinois Department of Healthcare and Family Services ("HFS").
- CountyCare provides coverage for any Cook County Medicaid eligible beneficiaries (ACA Adults, FHP, and SPD)
- Designed to transform CCHHS into a patient-centered continuum of care.
- Facilitated through CCHHS internal CountyCare staff and its various subcontractors.

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Yes…subcontractors…

- The CountyCare MCCN Contract defines "subcontractor" as an:

"*entity, other than a Provider, with which Contractor has entered into a written agreement for the purpose of delegating responsibilities applicable to Contractor under this Contract. When not used as a defined term, "subcontractor" means any subcontractor of Contractor, including Providers and Subcontractors*."

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Delegated Activities

- Subcontractors are delegated to carry out the following contractual responsibilities:
  - Member Communications
  - Appeals & Grievances
  - Utilization Management
  - Care Coordination and Management
  - Claims Processing and Management
  - Fraud Waste and Abuse (FWA)/Special Investigations Unit (SIU)
  - 24 Hour Nurse Call Line
  - Pharmacy Benefit Manager (PBM)

SUBCONTRACTOR OVERSIGHT – COMPLIANCE REQUIREMENTS

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Centers for Medicare & Medicaid Services, HHS Pt. 438

PART 438—MANAGED CARE

Subpart D—Quality Assessment and Performance Improvement

STRUCTURE AND OPERATION STANDARDS

438.214 Provider selection.
438.218 Enrollee information.
438.224 Confidentiality.
438.226 Enrollment and disenrollment.
438.228 Grievance systems.
438.230 Subcontractual relationships and delegation.

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42 CFR §438.230 says…

With regard to Subcontractors, Medicaid Plans must

- **Assess & Evaluate** – Pre-delegation to determine if the prospective subcontractor has the ability to perform the activities;
- **Contract** – Enter into a written agreement that (1) specifies the activities and responsibilities; and (2) define sanctions if the subcontractor's performance is inadequate;
- **Oversee** – Compare performance to contractual requirements on an ongoing basis;
- **Formally Review** – Establish a periodic review schedule to parallel State MCO laws and regulations and is consistent with industry standards; and
- **Take Corrective Actions** - if deficiencies or areas for improvement are identified.

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Medicaid Plans and Subcontractors

MUST have compliance plans that contain the 7-elements:

- Written policies, procedures, and standards of conduct.
- The designation of a compliance officer and a compliance committee that are accountable to senior management.
- Effective training and education for the compliance officer and the organization's employees.
- Open lines of communication between the compliance officer and the organization's employees.
- Disciplinary guidelines and enforcement of standards.
- Internal monitoring and auditing.
- Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the health plan's contract.

See 42 CFR §438.608

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MCCN Contract Requirements

- CountyCare's Contract mandates specific measures to ensure the proper oversight of subcontractor performance with respect to the:
  - The Quality Assurance Program ("QAP");
  - CountyCare Cultural Competence Plan;
  - Delegated Credentialing; and
  - Provider/Subcontractor Agreements.
- Process for subcontractor oversight must contain:
  - Pre-delegation audits;
  - Written contracts with subcontractors with certain terms;
  - Quarterly reviews of subcontractors performed by the CountyCare Oversight Committee;
  - Annual audits of all subcontractors.

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NCQA Requirements

- For delegated Quality Improvement (QI), Utilization Management (UM), Credentialing, Rights and Responsibilities and Member Connection activities, certain elements must be met to achieve NCQA accreditation.
- Elements include:
  - Written Delegation Agreement
  - Provision of Member Data
    Provisions for PHI
  - Pre Delegation Evaluation
  - Annual Review of the Program/Delegated Function
  - Opportunities for Improvement

COUNTYCARE SUBCONTRACTOR OVERSIGHT PROCESS

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Subcontractor Oversight Process

PRESENT STATE:

- Delegated Vendor Oversight Committee
- CountyCare Policies and Procedures
- CountyCare Training
- Subcontractor Contracting Process
- Review of Subcontractor Audits/Ad Hoc Assessments

FUTURE STATE:

- Subcontractor Risk Assessment
- Subcontractor Work Plan
- Subcontractor Auditing and Monitoring
- Subcontractor Annual Attestation

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Delegated Oversight Committee

- Meets quarterly/monthly
- Comprised of CountyCare and TPA staff
- Formal minutes kept
- Review benchmark data submitted by subcontractors to evidence compliance with contractual requirements and performance measures
- Review audits conducted by Subcontractors
- Essential for engaging stakeholders in the organization

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Oversight Policies and Procedures

- Procure subcontractor's policies and procedures to assess their processes.
- Also collect polices and procedures from subcontractors that outline THEIR processes. Review of these policies and procedures in process.

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Training Requirements

- Subcontractors **must** complete CountyCare training
  - Compliance Program
  - Fraud Waste and Abuse
  - HIPAA
  - Cultural Competency
- **OR** Subcontractor can submit their own training and CountyCare will review for adequacy.

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Subcontractor Contracting

- RFP Process
  - Review of RPF language to ensure that all contractual and regulatory requirements are reflected in scope of work.
- Pre Delegation Audit
  - Review RFP responses to ensure that all contractual and regulatory requirements can be met prior to contract award.
  - Communicate with subcontractor to receive documented evidence of written policies, procedures and processes.

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Each Element of the Contract is Critical

- Master Services Agreement/General Conditions Template
  - Contains template language to outline subcontractor responsibility and CountyCare oversight role.
  - Includes standard Business Associate Agreement
- CCHHS Compliance section in Template specifically outlines requirements for:
  - Review of and adherence to Code of Ethics
  - Completion of CCHHS Training
  - Allowance and cooperation during Compliance auditing and monitoring processes
  - Debarment and Suspension procedures

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Assessments and Audits

- Review of Subcontractor Audits
  - Review audits performed of subcontractors (and their subcontractors) for issues detected and corrective action.
  - Information presented to Vendor Oversight Committee
- Ad Hoc Assessments of Subcontractors
  - Review of policies/procedures regarding:
    - Sanction Screening/Exclusion Checks
    - Fraud Waste and Abuse Monitoring
    - Confidentiality of Patient Information

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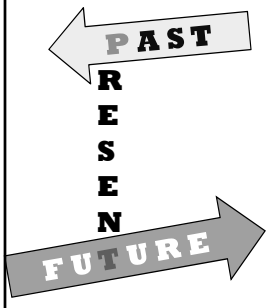
Considerations for Future State



- Subcontractor Risk Assessment
- Subcontractor Work Plan
- Subcontractor Auditing and Monitoring
- Subcontractor Annual Attestation

SUBCONTRACTOR OVERSIGHT TOOLKIT

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Tool Kit

- Policies/Procedures
- Simple contracting process
- Dashboard data received from subcontractors is key

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Main Takeaways

- Always “trust but verify”
- Documentation is key
- Monitoring process works best when the right data/information is communicated between parties.

Resources

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- 42 CFR §438.230. Subcontractual relationships and delegation.
- http://www.ecfr.gov/cgi-bin/text-idx?SID=61e755d649b4e964c97e5370a6095e7d&mc=true&node=se42.4.438_1230&rgn=div8
- 42 CFR §438.608. Program Integrity Requirements.
- http://www.ecfr.gov/cgi-bin/text-idx?SID=69c2bf5aea70f3abc8f0920278c9e89d&mc=true&node=se42.4.438_1608&rgn=div8
- CMS, Medicare Managed Care Manual (Pub. 100-16), Chapter 21. Compliance Program Guidelines, Section 40 – Sponsor Accountability for and Oversight of FDRs.
- https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf
- CMS, Medicare Advantage and Prescription Drug Compliance Program Effectiveness Self-Assessment and Questionnaire.
- https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Compliance-Program-Effectiveness-Self-Assessment-Questionnaire.pdf
- NCQA, Health Plan Accreditation Standards (2015). Interactive System.
- https://iss.ncqa.org/RDSat/ATMain.asp?ProductType=license&activityID=59202

Strategic Management Services, LLC

WRAP UP & QUESTIONS

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