THE IMPORTANCE OF PERFORMANCE MEASUREMENT, STAR RATINGS, AND COMPLIANCE ISSUES IN HEALTHCARE
FRIDAY, SEPTEMBER 2, 2016
QUALITY RATINGS IN HEALTHCARE
QUALITY RATINGS: WHAT IS BEING MEASURED?

Clinical Quality
- Patient Safety
- Prevention
- Effectiveness

Population Health

Experience of Care
Per Capita Cost

Plan Performance
- Plan Service
- Efficiency
- Affordability

Customer Experience
- Access
- Doctors & Medications
- Care & Coordination

Transparency
Publicly reported
Helps stakeholders & consumers make informed choices
Allows meaningful comparison of the performance of providers and managed care plans

Alignment
Use of a consistent approach across different programs
Supports more streamlined system that will support focus on value and outcomes
May result in economies of scale and more effective quality improvement

Consumer & Stakeholder Engagement
Supports more informed, more inclusive healthcare decision-making
Social, behavioral, and lifestyle factors influencing health must be addressed for success
Expansion into Medicare FFS and Medicaid will engage consumers and providers to help improve care and quality of life

KEY PRINCIPLES OF QUALITY MEASUREMENT & RATINGS
INCREASING FOCUS ON QUALITY IN HEALTHCARE

2016: MA Star Ratings in place for 17.6 million beneficiaries

2017: QHP QRS illuminates quality performance for another 12.7 million beneficiaries

2019: MACRA incorporates merit-based physician incentives for 39.4 million Medicare FFS beneficiaries

2021: Final Rule illuminates quality performance for 55.2 million Medicaid beneficiaries

RAPID DEPLOYMENT OF TARGETED QUALITY IMPROVEMENT ACTIVITIES BY PROVIDERS AND HEALTH PLANS

CMS’ USE OF QUALITY RATINGS

Measure and improve health plan quality
Help beneficiaries find the best plan for them
Determine quality bonus payments
Public reporting/ transparency
Basis for compliance and enforcement actions
Identification of audit candidates
Decisions for application approvals/denials
Contract terminations
KEY ELEMENTS OF QUALITY MEASUREMENT

- Preventive Care, Screenings, and Immunizations
- Chronic Condition Mgmt
- Clinical Practice
- Medication Mgmt
- Follow-up Care
- Outcomes
- Member Experiences & Perceptions

A NEW NORMAL FOR HEALTH PLANS & PROVIDERS

- Social Determinants of Health & Behavioral Influences on Health
- Lifestyle & Health Literacy
- Socioeconomic & Logistical Factors
- Clinical Complexities & Higher Incidence of Comorbidities
- Health Disparities
CMS publishes Star Ratings each year to measure quality in Medicare Advantage (MA) and Part D plans to assist beneficiaries in finding the best plan for them and to determine MA Quality Bonus Payments.

CMS posts Star Ratings of MA and Part D plans on Medicare Plan Finder (MPF) to provide Medicare beneficiaries with quality information about plans offered in their service area.

The Affordable Care Act (ACA) requires quality-based payments to be awarded to MA plans based on their Star Rating.
STAR RATINGS METHODOLOGY

• CMS’ payments to MA plans are linked to a plan’s Star Ratings performance.

• Higher-performing plans are paid more than lower-performing plans.

<table>
<thead>
<tr>
<th>What do the stars mean?</th>
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<tbody>
<tr>
<td>★★★★★ ★★★★ ★★★ ★★ ★</td>
<td>Excellent Above Average Average Below Average Poor</td>
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STAR RATINGS BACKGROUND

MA plans are awarded 1 to 5 stars on 47 measures in the following domains:

- Staying Healthy
- Managing Chronic Conditions
- Member Experience
- Members’ Complaints and Changes in Plan Performance
- Customer Service
- Drug Safety & Pricing
STAR RATINGS DATA SOURCES

- **Medical & Medication Claims**
  - Designed to allow consumers to compare performance to other plans and/or benchmarks
  - Measures are developed and maintained by National Committee for Quality Assurance (NCQA) and Pharmacy Quality Alliance (PQA)
  - Derived from: clinical claims, medication claims, diagnosis coding, medical records

- **Member Perception Survey**
  - Designed to evaluate enrollees’ perspectives on the services provided by health plans and providers
  - Focus on healthcare quality aspects that patients find important and are well equipped to assess
  - CAHPS is overseen by AHRQ; survey must be administered by a qualified vendor
  - Derived from: enrollee survey responses

- **Member Health Outcomes Survey**
  - Designed to measure a plan’s ability to maintain or improve the physical and mental health of its members over time
  - Focus on gathering clinically meaningful data with multiple uses to support improvements in healthcare quality
  - HOS is implemented by NCQA; survey must be administered by a qualified vendor
  - Derived from: enrollee survey responses

- **Administrative**
  - Designed to measure health plan performance across a variety of functional areas
  - Derived from: enrollment, spending, claims, and other administrative data

PROGRAM METHODOLOGY OVERVIEW

- **CMS assigns an overall Star Rating based on the weighted average of individual measure ratings.**

- **The measures contained in the Star Ratings program are weighted, with:**
  - process measures assigned a weight of 1
  - 1.5x-weighted patient experience and access measures
  - 3x-weighted outcomes and intermediate outcomes measures
  - 5x-weighted performance improvement measures

- **Contracts may improve Star Ratings from one year to the next, but not all contracts can significantly improve their Star Ratings because each measure is scored on a relative scale (bell curve).**

- **CMS conducts an annual review of Star Ratings measures, considering the reliability of the measures, clinical recommendations, feedback received from stakeholders, and data issues. Based on this review, measures may be added, removed, or adjusted at CMS’ discretion.**
**EXAMPLES: CURRENT QUALITY MEASURES**

<table>
<thead>
<tr>
<th>Staying Healthy</th>
<th>Managing Chronic Conditions</th>
<th>Member Experience with the Plan</th>
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</thead>
<tbody>
<tr>
<td>• Breast Cancer Screening</td>
<td>• SNP Care Management</td>
<td>• Setting Needed Care</td>
</tr>
<tr>
<td>• Colorectal Cancer Screening</td>
<td>• Care for Older Adults – Medication Review</td>
<td>• Setting Appointments and Care Quickly</td>
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<tr>
<td>• Annual Flu Vaccine</td>
<td>• Care for Older Adults – Functional Status Assessment</td>
<td>• Customer Service</td>
</tr>
<tr>
<td>• Improving or Maintaining Physical Health</td>
<td>• Care for Older Adults – Pain Assessment</td>
<td>• Rating of Healthcare Quality</td>
</tr>
<tr>
<td>• Improving or Maintaining Mental Health</td>
<td>• Osteoporosis Management in Women Who Had a Fracture</td>
<td>• Rating of Health/Drug Plan</td>
</tr>
<tr>
<td>• Monitoring Physical Activity</td>
<td>• Diabetes Care – Eye Exam</td>
<td>• Care Coordination</td>
</tr>
<tr>
<td>• Body Mass Index (BMI) Assessment</td>
<td>• Diabetes Care – Kidney Disease Monitoring</td>
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<tr>
<td></td>
<td>• Diabetes Care – Blood Sugar Controlled</td>
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<tr>
<td></td>
<td>• Medication Adherence for Diabetes Medications</td>
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<tr>
<td></td>
<td>• Controlling Blood Pressure</td>
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<td></td>
<td>• Medication Adherence for Hypertension</td>
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<td>• Medication Adherence for Cholesterol</td>
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<td></td>
<td>• Rheumatoid Arthritis Management</td>
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<td></td>
<td>• Reducing the Risk of Falling</td>
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<td></td>
<td>• Plan All Cause Readmissions</td>
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<td></td>
<td>• MTM Program Completion Rate for CMR</td>
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</tbody>
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* May be introduced as 2018 Star Measure (based on 2016 services)

**2017 AND BEYOND: CMS’ TARGET IS BROAD**

- Care Coordination (Data-Driven)
- Post-Discharge Medication Reconciliation*
- MPF Price Accuracy
- Reminders for Immunizations, Screening Tests, and Appointments
- Reminders to Fill Prescriptions or Take Medications
- Disenrollment Reasons
- Transition Monitoring

**Physician-Influenced**

- Asthma Treatment
- Depression Care
- Hospitalization for Potentially Preventable Complications*
- Statin Therapy
- High Risk Med Updates
- Pain Management
- Pharmacotherapy Mgmt of COPD Exacerbation
- Reminders for Immunizations & Appts
- Computer Use During Office Visits

**Member-Influenced**

- Asthma Medication Fill/Adherence
- Initiation and Engagement of Alcohol or Other Drug Treatment
- Pharmacotherapy Mgmt of COPD Exacerbation

* May be introduced as 2018 Star Measure (based on 2016 services)
The ACA requires CMS to use Star Ratings to reward highly-rated Medicare Advantage plans with Quality Bonus Payments (QBPs).

- QBPs are paid only to contracts rated at or above 4 Stars.
- QBPs are based on the overall Star Rating, rather than individual measure ratings.
- QBPs vary by health plan based on the contract’s benchmarks (the maximum amount Medicare will pay a plan in a specific county or region).
- QBPs are based on plan performance during the 2-3 years preceding the Star Rating.
**THE FINANCIAL VALUE OF STAR RATINGS**

1,000 Plan Members \( \times \) $10,000 Revenue per member per year = $10,000,000 Annual Revenue

0% Bonus = $0

5% Bonus = $500,000

If membership grows to 5,000 5% bonus would be $2,500,000.

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**BEYOND THE MONEY: A “VICIOUS CYCLE”**

4-Star threshold not achieved \( \rightarrow \) No bonus, less rebates

Poor survey results \( \rightarrow \) Loss of members; eroding satisfaction

Benefits suffer \( \rightarrow \) 4-Star threshold not achieved
COMPLIANCE, DATA INTEGRITY & STAR RATINGS

• CMS can reduce a measure to 1 star if:
  - Biased or erroneous data is submitted
  - An underlying compliance issue exists in the data

• Automatic assignment of a 2.5 star overall rating suspended pending CMS’ reevaluation of the impact of sanctions, audits, and civil money penalties (CMPs) on Star Ratings

• Important areas to monitor:
  - HEDIS, CAHPS, HOS, MPF, and PDE data requirements
  - ODAG and CDAG processes
  - Coverage disputes and complaints
  - MTM programs

• CMS’ search for new vulnerabilities continues!

A VISION FOR SUCCESS

Population Health
• Focused analytics & reporting
• Assess & stratify population
• Identify outliers & intervene with appropriate resources

Engagement, Execution, & Improvement
• Effectively targeted activities
• Strong Collaborations
• Address clinical & non-clinical issues

“Make It Work” Innovation
• Leverage every interaction with a member for Stars & non-Stars success
• Customize support for chronically ill

INTEGRATION & COORDINATION
THE ULTIMATE GOAL:
THE RIGHT INTERVENTION. THE RIGHT PATIENT. THE RIGHT TIME.

- Complex/acute co-morbidities
- Medication effectiveness
- Complex medication regimens
- Medication side effects

- Lack of food or housing
- Cost constraints
- Lack of transportation
- Reliance on caregivers

- Lack of motivation
- Absence of social support
- Lack of disease understanding
- Lack of trust in provider(s)
- Cultural sensitivities

- Poor mental health status
- Inability to make decisions
- Decreased cognitive function
- Forgetfulness
- Misguided peer support

Clinical Factors
Socioeconomic and Logistical Factors
Lifestyle and Literacy Factors
Social and Behavioral Factors

Strategy + Execution = SUCCESS

IMPROVING QUALITY MEASURE PERFORMANCE THROUGH NUTRITION & MEALS
**IMPROVING QUALITY THROUGH NUTRITION:**

**MEALS TO SUPPORT MEDICINE**

**HEAVILY-WEIGHTED QUALITY MEASURES DIRECTLY IMPACTED BY NUTRITION**

- Plan All-Cause Readmissions
- Improving or Maintaining Mental Health
- Diabetes Care – Blood Sugar Controlled
- Improving or Maintaining Physical Health
- Controlling Blood Pressure

**QUALITY MEASURES WHICH COULD BE INDIRECTLY IMPACTED BASED ON MOW HEALTHCARE INTEGRATION**

**SCREENINGS AND PROCESS**
- Breast and Colorectal Cancer Screening
- Annual Flu Vaccine
- Adult BMI Assessment
- Care for Older Adults – Functional Status Assessment
- Care for Older Adults – Pain Screening
- Diabetes Care – Eye Exam
- Diabetes Care – Kidney Disease Monitoring
- MTM CMR Completion

**HEALTHCARE SUPPORT**
- Monitoring Physical Activity
- Reducing the Risk of Falling
- Care Coordination

**MEDICATION ADHERENCE**
- Diabetes Medications
- Hypertension
- Cholesterol

**MEMBER PERCEPTIONS**
- Rating of Healthcare Quality
- Rating of Health Plan
- Members Choosing to Leave the Plan

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**EXAMPLE: CURRENT MA BENEFIT OPPORTUNITIES**

- Limited to: 4 weeks (post-discharge) or 2 weeks (after exacerbation of chronic condition)
- No out-of-pocket or referrals
- Provision of meals requires physician’s order
- Meals must be medically necessary
- Typically part of discharge planning for ease of administration
- Member utilization of benefit is voluntary

- Dual-eligible SNPs meeting certain criteria may also cover additional in-home meal services.
MEALS TO SUPPORT MEDICINE:
INNOVATION PATHWAYS ABOUND

- HEDIS Quality Measures
- Data Integrity
- Risk Adjustment
- Disease Management
- Social Support
- Disease Prevention
- Care Coordination
- Care Management
- Nutrition Counseling
- Medication Support
- Daily Living Support & Encouragement

MEALS TO SUPPORT MEDICINE:
ESTABLISHING A STRATEGY

**Nutrition Services**
- Meal Delivery

**The Value Proposition**
- Change of Condition Monitoring & Alerts
- In-home Health Outcomes Support
- Health Plan Support

**Highest Return on Investment Service Opportunities**
- Identify and support barriers to blood sugar & blood pressure control
- Schedule in-home gap closure (screenings, MTM, coaching)
- Provide navigation social and lifestyle support services
- Support transitions of care
- Complete CAHPS/HOS proxy survey
- Offer nutrition, exercise & other classes in congregate settings

- Validate phone, address, email, PCP data
- Complete HRA

**The Value Proposition**

**Highest Return on Investment Service Opportunities**

- Identify and support barriers to medication adherence
- Schedule in-home gap closure (screenings, MTM, coaching)
- Provide navigation social and lifestyle support services
- Support transitions of care
- Complete CAHPS/HOS proxy survey
- Offer nutrition, exercise & other classes in congregate settings

- Validate phone, address, email, PCP data
- Complete HRA
MEALS TO SUPPORT MEDICINE IN REGULATED HEALTHCARE

Evolving Infrastructure & Culture:
- Selecting the opportunities to be pursued with MCOs and providers
- Billing and reporting tools
- Standardized workflows for contracted services
- ROI analysis of potential new contracts
- Formalized oversight and performance monitoring
- Workflows to optimize health plan “pull through”
- Resources and work plan to support health plan membership in any county not currently serviced
- Volunteer training and support
- Potential operational adjustments to meet contract terms

Incorporating Key Elements:
- Detailed descriptions of services in each contract
- Detailed procedures for failed deliveries, care alerts, etc., in each contract
- MCO service area changes after contracts in place
- Monitoring and adaptation to regulatory changes
- Increased training and support for local programs

THE BUSINESS SIDE OF PROVIDING MEALS TO SUPPORT MEDICINE
RESULTS SPEAK FOR THEMSELVES. SELL WHAT YOU (AND THEY) CAN MEASURE.

- Leverage existing evidence of the value of meals, nutrition, and the social visit from completed pilots, peer-reviewed literature, and reliable industry white papers:
  - Reduced readmissions offers immediate reduction in medical costs
  - Improved health outcomes offers longer-term control of medical costs
- Structure data collection amidst new contracts to collect and analyze outcomes. Examples could include things such as:
  - Improved quality measure rates by scheduling services to close gaps
  - Improved revenue by reconciling members with enrollment
  - Reduced cost for emergency room visits by better supporting member’s use of PCP or urgent care (where appropriate)
  - Improved pharmacy cost management through medication management and coordination

LOCAL PROGRAM COMPLIANCE = MCO COMPLIANCE
LOCAL PROGRAM SUCCESS = MCO SUCCESS

OPERATIONALIZING INNOVATION

- CULTURAL EVOLUTION
  - Develop strong health plan and provider relationships to support consistent, compliant execution of well-defined workflows.
  - Prepare for real-time adaptation of contracted services and workflows to comply with regulatory updates.
  - Consistently monitor and carefully evaluate potential sales opportunities.
  - Carefully-design MCO services to ensure they will:
    - Have desired impact on quality ratings and cost
    - Outlast the continual change in regulated healthcare.

- BUSINESS ACUMEN
  - Effective MCO contracting is vital:
    - Prescriptive service expectations, including remote geographies, missed/rejected deliveries, follow-up
    - Billing, payment, and reporting requirements
    - Assess risks of P4P/outcomes-based contracts
    - Pricing and profitability for both MOWA and local programs, including direct costs and overhead
    - “Cash float” between cash outflows and payment
    - Volume expectations
    - Approval of services by local program(s)
  - Administrative and “back-office” staffing, infrastructure, processes, and internal controls to fulfill and administer contracts.
  - Prediction and management of potential volume fluctuations which may occur under new contracts.
SUPPORTING AN EXPANDING MISSION

• After services are rendered under new contracts:
  o May receive increased referrals for long-term meal deliveries after contractual service is complete.
  o May receive increased referrals for long-term meal deliveries from health plan social workers and case managers as awareness of benefits increases.

• Prepare to consider:
  o Increased pursuit and coordination of corporate fundraising and volunteerism to support needs of local programs, particularly those participating in regulated healthcare initiatives.
  o Development of grant application, administration and oversight infrastructure to support local program activities within the context of available funding opportunities.
THE CONTINUED EVOLUTION OF HEALTH PLAN PARTNERSHIPS

EXPANDING SERVICES TO IMPACT QUALITY MEASURES

• Have you considered opportunities to use meals and a face-to-face visit with a senior to help improve quality and Star Ratings in your service area?
• Have you considered contracting with MCOs or provider groups to support their quality efforts?
• What are your local providers’ and health plans’ quality and Star Ratings “pain points?” Are there opportunities for you to help?
• How might you be able to expand your face-to-face visit with a senior in high-value, high-impact?
### EXPANDING SERVICES TO IMPACT HEALTHCARE QUALITY: KEY CONSIDERATIONS

<table>
<thead>
<tr>
<th>Flexibility</th>
<th>Cross-functional, comprehensive collaboration</th>
<th>Scalability and sustainability</th>
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</table>
| • to account for constantly changing program requirements and measures  
• to accommodate variations in health plan priorities, preferences, and business decisions  
• to enable customization by health plan, member, provider, and/or local market |
| • between health plans and their providers, vendors, and staff  
• among all internal and external organizations leveraging available tools and resources wherever needed  
• through processes which incorporate social determinants of health |
| • using data from disparate data sources to support person-centered care and interventions  
• leveraging face-to-face social interaction with meal recipient to support patient-centered services |

### OPEN DISCUSSION

*The pessimist complains about the wind.*  
*The optimist expects it to change.*  
*The leader adjusts the sails.*
- Health Information Security and Compliance
  - Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), significantly amended and expanded by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH").
    - Privacy Rule
    - Security Rule
    - Breach Notification Rule
- Fraud, Waste and Abuse
  - First Tier, Downstream and Related Entities Medicare Compliance
The purpose of HIPAA is:
- To improve the efficiency and effectiveness of the healthcare system.
- Standardizing and protect the communication of health information, with particular regard to privacy, security and electronic data interchange.

HIPAA applies to certain covered entities, including certain health care providers, health plans and health care clearinghouses. Because Meals on Wheels programs provide medically necessary services and because they furnish, bill, or receive payment for health care in the normal course of business, they are covered by HIPAA.

As a “business associate,” to a covered entity, Meals on Wheels programs are subject to HIPAA and HITECH.
- A “business associate” is an independent contractor or agent of a covered entity that receives or obtains protected health information (“PHI”) in connection with the services it provides for the covered entity.

HITECH and the Omnibus Rule made many HIPAA obligations applicable to business associates of covered entities

Business Associate agreements dictate requirements imposed on contractors, including HIPAA compliance.
HIPAA RULES

Key regulations include, among others:

- **Privacy Rule**: defines standards and requirements for the protection, use and disclosure of all individually identifiable, PHI held or transmitted by a covered entity in any form (e.g. paper, electronic, oral).

- **Security Rule**: establishes standards for securing PHI that is held or transferred in electronic form.

- **Breach Notification Rule**: requires notification by business associates to covered entities – and by covered entities to the government, media, and affected individuals – of certain breaches of secured PHI.

HIPAA PRIVACY RULES

**Privacy rule**

- Defines and limits circumstances in which covered entities like Meals on Wheels America and local programs may use and disclose PHI;
- Establishes individuals' rights regarding PHI; and
- Requires that Meals on Wheels programs adopt administrative, physical, and technical safeguards to protect the privacy of PHI

**PHI** is any information, transmitted or maintained in any form or medium, that a covered entity creates or receives and relates to the:

- past, present or future physical or mental health or condition of an individual,
- provision or health care to individual, or
- past, present or future payment for the provision of health care to an individual and that identifies the individual.
HIPAA PRIVACY RULE

Common PHI which you may use daily includes:

- Names
- Telephone/Facsimile Numbers
- Medical/Health Plan Numbers
- Dated (e.g. DOB, dates of treatment)
- E-mail Addresses
- Social Security Numbers
- Addresses and geographic information
- Medical Conditions
  - Diagnoses
  - Treatments
  - Prescriptions
  - Referrals

INDIVIDUAL RIGHTS REGARDING PHI

- HIPAA gives individuals rights that increase their ability to control their PHI, including rights to:
  - Notice of Privacy Practices *(provided by covered entities)*;
  - Request Privacy Protection for PHI;
  - Request Access to PHI;
  - Request Amendment of PHI; and
  - An Accounting of Disclosures of PHI
- By entering into a business associate agreements with covered entities, Meals on Wheels America/programs are required to assist covered entities in respecting individuals’ rights. Our obligations are determined by the terms of those business associate agreements with covered entities in addition to HIPAA/HITECH requirements.
HIPAA PRIVACY RULE

RIGHT TO NOTICE OF PRIVACY

• A “Notice of Privacy Practices” (NPP) must be provided to all patients by our “covered entity” customers.

• Business associate agreements with covered entities obligate us to abide by certain HIPAA/HITECH obligations consistent with NPPs.

• Meals on Wheels is also directly subject to government regulations regarding compliance with HIPAA/HITECH requirements.

HIPAA PRIVACY RULE

RIGHT TO REQUEST PRIVACY PROTECTION

• Individuals may request restrictions on uses and disclosures of their PHI. However, such requests do not apply to:
  • Use of PHI for treatment, payment or health care operations (“TPO”);
  • Emergency treatment of the individual;
  • Individuals accessing their own PHI;
  • Requests for an accounting of disclosures of PHI; or
  • Release as required by law.

• Individuals may request:
  • PHI to be delivered in a secure and confidential manner; and
  • Communication of PHI by alternative means and locations.

• Covered entities must agree to individuals’ requests to restrict disclosure of PHI about the individual to a health plan if:
  • The disclosure is for carrying out payment or health care operations and is not otherwise required by law; and
  • The PHI pertains only to a health care item or service for which the individual (or person his/her behalf besides the health plan) has fully paid the covered entity.
HIPAA PRIVACY RULE

RIGHT TO AN ACCOUNTING OF DISCLOSURES OF PHI

• Individuals may request an accounting of:
  • Uses or disclosures of their PHI, for purposes other than TPO purposes (unless covered entity uses electronic health records), disclosures to the individual, and/or disclosures pursuant to an authorization.
  • Disclosures made six years prior to request (only three years for disclosures through an Electronic Health Record, as defined in Section 13400 of HITECH, to carry out TPO).

• Each accounting must be in writing and include:
  • Date of disclosure;
  • Name of entity or person who received PHI;
  • Brief description of PHI disclosed; and
  • Brief statement of purpose of the disclosure.

HIPAA PRIVACY RULE

RIGHT TO ACCESS / RIGHT TO AMEND PHI

• Individuals may request access to inspect and/or obtain a copy of their PHI.
• Individuals may request an electronic copy of their PHI and may request a particular form and format.
• Individuals may request an amendment to their PHI.
• Individuals may direct a copy of their PHI to be transmitted directly to another person designated by the individual in writing, signed by the individual, and clearly identifying the designated person and where to send the copy of the PHI.
HIPAA PRIVACY RULE

USE AND DISCLOSURE OF PHI

• Meals on Wheels programs may not use or disclose clients’ PHI for any purposes it chooses.
• We only may use or disclose PHI to:
  • Provide services to our covered entity customers, as prescribed by our services agreements and our business associate agreements with these customers;
  • For proper management and administration, if permitted by business associate agreement with the applicable covered entity; and
  • When required by law.

ADMINISTRATIVE REQUIREMENTS

• Designate a Privacy Officer
• Train employees
• Implement safeguards to prevent intentional and accidental disclosures
• Establish a complaint system
• Sanction employees who violate HIPAA policies and procedures
HIPAA PRIVACY RULES

HIPAA PRIVACY POLICIES

- Privacy Officer
- Documentation Requirements
- Minimum Necessary PHI
- Permitted Uses and Disclosures of PHI
- De-Identified Information
- Business Associate Agreements
- Privacy Policy Revision
- Training
- Sanctions
- Complaints and Concerns
- Retaliation
- State Law
- Privacy Policy Revision

AGENDA

- Health Information Security and Compliance
  - Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), significantly amended and expanded by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”).
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  - First Tier, Downstream and Related Entities Medicare Compliance
SECURITY RULE

Overview
- As a business associate, the Security Rule requires Meals on Wheels America / programs to:
  - Ensure the confidentiality, integrity and availability of electronic PHI ("E PHI") that it creates, receives, maintains or transmits;
  - Protect against reasonably anticipated threats or hazards to the security or integrity of EPHI; and
  - Protect against uses or disclosures that are not permitted by the Privacy Rule

SECURITY RULE

Requirements
- Required Safeguards
  - Administrative safeguards
  - Physical safeguards; and
  - Technical safeguards.
- In each category, specific standards are prescribed by law, and these need to be incorporated into Meals on Wheels policies and procedures
## SECURITY RULE

### Administrative Safeguards
- Security management process
- Assigned security responsibility
- Workforce security
- Information access management
- Security awareness and training
- Security incident procedures
- Contingency plan
- Evaluation
- Business associate contracts and other arrangements

### Physical Safeguards
- Facility access controls
- Workstation use
- Workstation security
- Device and media controls
SECURITY RULE

Technical Safeguards
• Access controls
• Audit controls
• Integrity measures
• Person or entity authorization
• Transmission security

SECURITY RULE

Responsibilities
• Respect all organizational policies regarding access/security
• Never share your computer password
• Assure that you sign off of applications containing EPHI after use
• Secure (encrypt) portable electronic devices, such as USB thumb-drives or laptops, that contain EPHI
• Avoid using individuals’ names, medical record numbers or account numbers in unencrypted emails
• Promptly report any loss or theft of electronic devices that contain EPHI
• Promptly inform Privacy Officer of any improper uses of EPHI
SECURITY RULE

Policies and Procedures

- Security Officer
- Documentation Requirements
- Risk Analysis
- Risk Management
- Information System Activity Review
- Malicious Software
- User Identification
- Password Management
- Log-in Monitoring
- System Access
- Facility Access / Physical and Environmental Access
- Security Incident Response
- Business Contingency and Continuity Plan
- Security Evaluation

- Subcontractor Agreement
- Asset Management
- Device and Media Controls
- Equipment Movement / Removable Storage Devices
- Automatic Logoff
- Encryption
- Authentication of ePHI
- Security Breaches
- Training
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BREACH NOTIFICATION RULE

- Breach is defined as:
  - Unauthorized acquisition, access, use or disclosure of PHI
  - That compromises its data privacy or security
- A breach is presumed
  - Unless the covered entity or the business associate, as applicable, demonstrates a low probability that the PHI has been compromised based on a risk assessment
- Applies to all electronic “unsecured PHI”
  - EPHI is “unsecured” if it is not encrypted or destroyed
- As a business associate, in event of a breach, Meals on Wheels America is required to notify its covered entity customers.

PENALTIES FOR NON-COMPLIANCE

- HITECH significantly increased penalties
  - Civil
  - Criminal
- Tiered penalty structure with scalable penalties based on the nature and circumstances of the violation, including knowledge and willfulness
  - Curing/correcting a violation promptly and within 30 days of identification may reduce potential penalties substantially
- Government and individual incentives exist to encourage complaints/enforcement
- Breach notification requirements make breaches public
PENALTIES FOR NON-COMPLIANCE

- Mandatory penalties range from $100 to $50,000 or more per violation, depending on the level of knowledge/intent associated with violation
- Overall limit of $1.5 million for identical violations during calendar year
- Employees of a business associate such as Meals on Wheels America, who knowingly disclose PHI in violation of HIPAA, as amended by HITECH, can be fined between $50,000 to $250,000 and imprisoned for up to 10 years depending on level of intent behind disclosure
  - Offenses committed with intent to sell, transfer, or use PHI for commercial advantage, personal gain or malicious harm carry higher penalties

AGENDA

- Health Information Security and Compliance
  - Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), significantly amended and expanded by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH").
    - Privacy Rule
    - Security Rule
    - Breach Notification Rule
- Fraud, Waste and Abuse
  - First Tier, Downstream and Related Entities Medicare Compliance
FRAUD, WASTE AND ABUSE

- **Fraud** is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. 18 U.S.C. § 1347.

- **Waste** is the overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of services.

FRAUD, WASTE AND ABUSE

- **Abuse** includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud, because the distinction between “fraud” and “abuse” depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.

- **Federal laws and regulations** designed to prevent or ameliorate fraud, waste, and abuse to include but not limited to:
  - Applicable provisions of Federal criminal law;
  - The False Claims Act (31 U. S.C. 3729 et seq.);
  - The Anti-Kickback statute ( § 1128B(b) of the Act); and,
  - HIPAA administrative simplification rules at 45 CFR Parts 160, 162, and 164.
  - See also: the January 11, 2013, Compliance Program Guidelines n Chapter 21 of the Medicare Managed Care Manual (manual).
FRAUD, WASTE AND ABUSE – SPONSOR OBLIGATIONS

MA Plan Sponsors must demonstrate a commitment to compliance, integrity, and ethical values as demonstrated by the following:

1. Written policies, procedures, and standards of conduct;
2. The designation of a compliance officer and compliance committee;
3. Effective training and education between the compliance officer and employees;
4. Effective lines of communication between the compliance officer, employees, and MA-related contractors to obtain and share information;
5. Enforcement of standards through well-publicized disciplinary guidelines;
6. Provision for internal monitoring and auditing that includes a risk assessment; and,
7. Procedures for ensuring prompt response to detected offenses.

FRAUD, WASTE AND ABUSE – SPONSOR OBLIGATIONS

- Each sponsor must implement an effective compliance program that meets the regulatory requirements set forth at 42 C.F.R. §§422.503(b)(4)(vi) and 423.504(b)(4)(vi). Sponsors should apply the principles outlined in these guidelines to all relevant decisions, situations, communications and developments.
FRAUD, WASTE AND ABUSE – SPONSOR OBLIGATIONS

- The sponsor’s compliance officer, working with the sponsor’s compliance committee, must develop procedures to promote and ensure that all FDRs are in compliance with all applicable laws, rules and regulations with respect to Medicare Parts C and D delegated responsibilities.

- The sponsor must have a system in place to monitor FDRs. Sponsors are free to choose the method for monitoring their FDRs’ compliance with Medicare program requirements.

- Sponsors must be able to demonstrate that their method of monitoring is effective.

FRAUD, WASTE & ABUSE – SPONSOR ACCOUNTABILITY

- The sponsor maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS, and for meeting the Medicare program requirements.

- CMS may hold the sponsor accountable for the failure of its FDRs to comply with Medicare program requirements.

- Medicare program requirements apply to FDRs to whom the sponsor has delegated administrative or health care service functions relating to the sponsor’s Medicare Parts C and D contracts.
FRAUD, WASTE & ABUSE – FDR RESPONSIBILITIES

• Your organization and all of your Downstream Entities must comply with Medicare compliance program requirements.

• These Medicare compliance program requirements include, but are not limited to:
  - Effective January 1, 2016, completion of the CMS FWA training and the CMS general compliance training modules
  - Code of conduct/compliance program policy distribution
  - Exclusion list screenings
  - Reporting of FWA and compliance concerns
  - Offshore operations and CMS reporting
  - Specific federal and state compliance obligations
  - Monitoring and auditing of FDRs

FRAUD, WASTE & ABUSE – FDR RESPONSIBILITIES

• Attestation requirements. Evidence of compliance with these Medicare requirements (for example, employee training records and CMS certificate of FWA training completion) must be maintained for no less than 10 years. An authorized representative must attest to this compliance. This individual could be the compliance officer, chief medical officer, practice manager/administrator, an executive officer or someone in a similar position who has responsibility directly or indirectly for all:
  • Employees
  • Contracted personnel
  • Providers/practitioners
  • Vendors who provide health care and/or administrative services for Medicare plans
• You may be asked to provide evidence of compliance in addition to completing an attestation.
FRAUD, WASTE & ABUSE – TRAINING 1

- Complete the modules on the CMS Medicare Learning Network (MLN) website. The general compliance course is called Medicare Parts C and D General Compliance Training, and the FWA training is called Combating Medicare Parts C and D.
- Develop your own for your organization by downloading the content of the CMS training modules from the Medicare Learning Network (“MLN”) website to incorporate it into your training materials/system.

FRAUD, WASTE & ABUSE – TRAINING 2

- **Compliance training requirements**
  - Regardless of the method used, the training must be completed:
    - Within 90 days of initial hire or the effective date of contracting
    - At least annually thereafter
- Your compliance with these requirements would normally be confirmed part of the annual attestation process. However, evidence of training completion, such as training logs or reports that include courses completed, employee names, dates of employment, dates of completion, must also be maintained.
FRAUD, WASTE & ABUSE – CODE OF CONDUCT

- Your organization must also either adopt the Sponsor’s Code of Conduct and Medicare compliance policies or create your own comparable version for all employees and Downstream entities who provide administrative and/or health care services. Standards of Conduct must be distributed:
  - Within 90 days of hire or the effective date of contracting
  - When there are updates to the standards of conduct
  - Annually thereafter
- Also, you must retain evidence of your distribution of the standards of conduct.

FRAUD, WASTE & ABUSE – EXCLUSIONARY SCREENING

- Before hiring or contracting, and monthly after that, each FDR must check exclusion lists from the Office of Inspector General (OIG) and General Services Administration (GSA) to confirm that employees and Downstream Entities aren’t excluded from participating in federally funded health care programs.
  - OIG List of Excluded Individuals and Entities (LEIE)
    - https://oig.hhs.gov/exclusions/index.asp
  - GSA’s System for Award Management (SAM)
    - https://www.sam.gov/portal/SAM/##11#1
- Also, FDRs must maintain evidence that these exclusion lists were checked.
FRAUD, WASTE & ABUSE – OTHER MATTERS

• Report fraud, waste and abuse – an effective means for reporting concerns to the sponsor needs to be established.

• Service providers must have effective policy and enforcement capability to ensure there is no retaliation or intimidation against anyone who reports suspected misconduct.

• Compliance with state laws – there may be state and local laws which may affect your provision of services; it is up to the vendor to know.

FRAUD, WASTE & ABUSE – TRAINING LINKS

• CMS - 2016 Compliance and FWA Training Update.pdf

• CMS Training Element 1 - Policies Procedures Standards of Conduct.pdf

• CMS Training Element 1 - Update and Supplement to Policies Procedures Standards of Conduct

• CMS Training Element II - Compliance Officer, Committee and High Level Oversight

• CMS Training Element III - Effective Training and Education.pdf

• CMS Training Element IV and V - Lines of Communication Disciplinary Standards.pdf

• CMS Training Element VI - Monitoring Auditing of Compliance Risks.pdf

• CMS Training Element VI - Supplement on Monitoring Auditing of Compliance Risks.pdf

• CMS Training FWA - Prevention Detection and Reporting.pdf
MEALS ON WHEELS AMERICA CONTACT

We are here to help!

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