Medication Therapy Management: A New Era in Pharmacy Practice

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Objectives

1. Describe MTM and its objectives.
2. Define Comprehensive Medication Review (CMR) and its application to different practice settings
3. Identify the eligibility for enrollment, targeted beneficiaries, and the number of participants previous years.
4. Discuss the application of the Affordable Care Act (ACA)
5. Describe the submission process and requests to change the policy from the point of view of the sponsors.
6. Discuss policy options that could support enhancing MTM programs.
Disclosures

- The speakers have no disclosures to make
What is MTM?

- As defined in a consensus definition adopted by the pharmacy profession in 2004, medication therapy management is a service or group of services that optimize therapeutic outcomes for individual patients. (APhA)

- Goals
  - Improve Medication adherence
  - Improve Quality of Care
  - Actively managing drug therapy and by identifying, preventing and resolving medication-related problems.

- Medication therapy management services can include
  - Medication therapy reviews
  - Pharmacotherapy consults
  - Anticoagulation management
  - Immunizations
  - Health and wellness programs and
  - Many other clinical services.
What is the need for MTM?

- Address adherence and Adverse Drug Events (ADE) in a growing “at-risk” population
  - Today there are over 43.1 million adults aged 65 and older in the United States; by 2040, that number will rise to 79.7 million.
  - Experts estimate that 1.5 million preventable adverse events occur each year that result in $177 billion in injury and death.
  - 31% of all initial drug prescriptions were not filled within nine months\(^1\)

What is the need for MTM? (cont.)

- Hospital admissions cost $121.5 billion
- Long-term care admissions cost $32.8 billion
- Physician visits cost $13.8 billion
- Emergency department visits cost $5.8 billion
- Additional treatments cost $3.5 billion
- An additional $24 billion is spent on medication-related problems in other settings
- $20 billion in acute care facilities, such as hospitals

What is the need for MTM? (cont.)

Contributing factors

- Nearly 92% of older adults have at least one chronic condition, and 77% have at least two.
- Some type of disability (e.g. difficulty in hearing, vision, cognition, ambulation, self-care, or independent living) was reported by 36% of adults aged 65 and over in 2012.
- 42% of patients 65 and older took 5 or more medications in 2012.
- The average number of medications increases from 5 to 7 by age 85.

What can MTM Do?

- Clinical and economic outcomes of medication therapy management services: the Minnesota experience.


- Patients receiving face-to-face MTM services provided by pharmacists in collaboration with prescribers experienced improved clinical outcomes and lower total health expenditures. Clinical outcomes of MTM services have chronic care improvement and value-based purchasing implications, and economic outcomes support inclusion of MTM services in health plan design.
What can MTM Do? (cont.)

- The Asheville Project: Clinical and Economic Outcomes of a Community-based Long-term Medication Therapy Management Program for Hypertension and Dyslipidemia

- Patients with HTN and/or dyslipidemia receiving education and long-term MTM services achieved significant clinical improvements that were sustained for as long as 6 years, a significant increase in the use of CV medications, and a decrease in CV events and related medical costs.
MTM: A Brief History

- Medicare Part D Medication Therapy Management (MTM) programs have included expanded program requirements since 2010, and additional MTM improvements have been implemented to further strengthen these programs through provisions of the Affordable Care Act (ACA).

- The Medicare Modernization Act of 2003 (MMA) established the requirements that Part D sponsors must meet with regard to cost control and quality improvement including requirements for MTM programs.

- After an extensive analysis, the requirements were expanded in 2010 for increased consistency among the programs, and CMS pushed the industry forward.
  - Significant changes were made to the targeting criteria and CMS required a minimum level of MTM services that must be offered to the Part D beneficiaries who qualify for these programs.
MTM: Federal Regulation

- Under Federal Regulations, a Part D sponsor must have established a Medication therapy management program (MTMP) that –
  - Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use;
  - Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries;
  - May be furnished by a pharmacist or other qualified provider; and
  - May distinguish between services in ambulatory and institutional settings.

- Must enroll targeted beneficiaries using an opt-out method of enrollment only.
- Must target beneficiaries for enrollment in the MTMP at least quarterly during each plan year.
- Must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP.

42 CFR 423.153
MTM: Federal Regulation (cont.)

- Required minimum level of medication therapy management services
  - Interventions for both beneficiaries and prescribers.
  - Annual comprehensive medication review with written summaries
  - Quarterly targeted medication reviews with follow-up interventions when necessary.
  - Standardized action plans and summaries that comply with requirements as specified by CMS for the standardized format
MTM: Federal Regulation (cont.)

- **Annual comprehensive medication review** with written summaries
  - The beneficiary's comprehensive medication review--
    i. Must include an *interactive, person-to-person, or telehealth consultation* performed by a pharmacist or other qualified provider; and
    ii. May result in a recommended medication action plan.

- If a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate, the pharmacist or other qualified provider may perform the comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual.
MTM: Federal Regulation (cont.)

- Targeted beneficiaries
  - **Have multiple chronic diseases**, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment.
  
  - **Are taking multiple Part D drugs**, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment.
  
  - Are likely to incur the designated annual Part D drug costs (e.g. For 2011, costs for covered Part D drugs greater than or equal to $3,000)
MTM: Federal Regulation (cont.)

Figure 1. Percent of 2014 MTM Programs with Minimum Number of Multiple Chronic Diseases

- All contracts: 84.8% for 3 Diseases, 15.2% for 2 Diseases
- MA-PDs: 85.9% for 3 Diseases, 14.1% for 2 Diseases
- PDPs: 80.5% for 3 Diseases, 19.5% for 2 Diseases
- MMPs: 74.1% for 3 Diseases, 25.9% for 2 Diseases

Tables and Figures are from the 2014 CMS Report on MTM
Figure 2. Percent of 2014 MTM Programs with Top Ten Targeted Diseases

- Diabetes: 99.7%
- Chronic Heart Failure (CHF): 94.0%
- Dyslipidemia: 91.1%
- Hypertension: 89.8%
- Osteoporosis: 64.6%
- Chronic Obstructive Pulmonary Disease (COPD): 58.2%
- Asthma: 57.4%
- Depression: 42.6%
- Rheumatoid Arthritis: 32.4%
- End-Stage Renal Disease (ESRD): 14.1%
### MTM: Federal Regulation (cont.)

#### Table 2. Percent of 2014 MTM Programs by Minimum Number of Covered Part D Drugs

<table>
<thead>
<tr>
<th>Minimum Number of Covered Part D Drugs</th>
<th>% of all MTM Programs</th>
<th>% of MA-PD MTM Programs</th>
<th>% of PDP MTM Programs</th>
<th>% of MMP MTM Programs</th>
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<td>51.7%</td>
<td>54.6%</td>
<td>32.5%</td>
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</table>
Considerations in pharmacy fees. – Sponsors must:

- Describe in its application how it takes into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs under a Part D plan.

- Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTMP services to pharmacists and others upon request.
MTM: Federal Regulation (cont.)

![Bar chart showing the percentage of 2014 MTM programs provided by different types of providers.](chart.png)
MTM & THE 5 STAR SYSTEM

- **CMS grades Medicare prescription drug plans**, using its Five-Star Quality Rating System to measure performance and track patient outcomes.
- Medicare STAR Ratings have placed great emphasis on **quality-based metrics**.
- Star ratings are basis for monitoring quality and performance of Medicare plans and **tied to quality bonus payments**
- Ratings based on different input including:
  - Medical and drug plan data
  - Member surveys
In 2012, CMS started a three-year demonstration project for Medicare Advantage plans wherein CMS awards “quality bonus payments” (QBPs) to plans based on the plan’s star ratings.

Under the demonstration, plans must receive at least 3 stars to be eligible for QBPs.

The amount of QBP is determined by the star rating wherein higher stars equate to higher payments to the plans.

- For example, 3-star plans will receive a 3% QBP, 4-star plans receive a 4% QBP, and 5-star plans receive a 5% QBP.
- Assuming that the base payments for Medicare Advantage plans will not increase in future years, the QBPs may be the lynchpin to continued profitability for those plans.
MTM & THE 5 STAR SYSTEM (cont.)

- For each of the Star measures, CMS assigns a Star rating on a 1-5 scale:
- Star rating assigned utilizing statistical methods comparing health plans
- Predetermined thresholds
  - Set when industry standard has been established
  - Define expectation of high quality plan and drive quality improvement
- When a threshold is not established, distribution of data is used to assign Star ratings
Medicare health plans are rated on how well they perform in five different categories:

- Staying Healthy: Screenings, Tests, and Vaccines
- Managing Chronic (Long-Term) Conditions
- Plan Responsiveness and Care
- Member Complaints, Problems Getting Services, and Choosing to Leave the Plan
- Health Plan Customer Service

There are a total of 37 star measures for health plans (MAPs/ Part C)
Medicare drug plans are rated on how well they perform in four different categories (domain ratings):
- Drug Plan Customer Service
- Member Complaints, Problems Getting Services, and Choosing to Leave the Plan
- Member Experience with Drug Plan
- Drug Pricing and Patient Safety

There are a total of 18 star measures for drug plans (Part D)
CMS on MTM

- A CMS-approved MTM program is one of several required elements in the development of a Medicare Part D sponsor’s bid.
- CMS evaluates each program description as part of a Part D quality improvement requirement (42 CFR §423.153(d)), to ensure that it meets the current minimum requirements for the program year.
CMS on MTM (cont.)

- In 2014, there are 686 active Part D contracts with an approved MTM program.
  - 582 Medicare Advantage prescription drug plans (MA-PDs).
  - 77 standalone prescription drug plans (PDPs), including Employer contract MTM programs.
  - 27 Medicare-Medicaid Plans (MMPs).
CMS on MTM (cont.)

- Encouraged sponsors to offer MTM services to beneficiaries who fill at least one anti-hypertensive medication, to support the Million Hearts Initiatives.
- Encouraged beneficiaries to complete their annual comprehensive medication review (CMR) prior to their annual wellness visit, and bring their CMR summary to their medical visits.
- Encouraged sponsors to adopt standardized health information technology (HIT) for documentation of MTM services.
- Provided guidance and additional clarification to improve the delivery of MTM in long-term care (LTC).
Impact on Pharmacies

- Several of the health plan domains have star measures that are impacted by pharmacy services
  - **Domain: 1 - Staying Healthy: Screenings, Tests and Vaccines**
    - Measure: C06 - Annual flu vaccine
  - **Domain: 2 - Managing Chronic (Long Term) Conditions**
    - Measure: C11 – Care for Older Adults – Medication Review
    - Measure: C14 – Osteoporosis Management
    - Measure: C17 – Diabetes Care – Blood Sugar Controlled
    - Measure: C18 – Diabetes Care – Cholesterol Controlled
    - Measure: C19 – Controlling Blood Pressure
    - Measure: C20 – Rheumatoid Arthritis Management
Impact on Pharmacies (cont.)

- Similarly, drug plan domains also have star measures that are impacted by pharmacy services
  - Domain: 4 - Drug Pricing and Patient Safety
    - Measure: D14 - High Risk Medication
    - Measure: D15 - Diabetes Treatment
    - Measure: D16 – Part D Medication Adherence for Oral Diabetes Medications
    - Measure: D17 – Part D Medication Adherence for Hypertension Medications (RAS Antagonists)
    - Measure: D18 – Part D Medication Adherence for Cholesterol Medications (Statins)
Impact on Pharmacies (cont.)

- The five medication-use measures that are weighted the heaviest focus on medication safety and adherence in:
  - Members age 65 and older on medications with high risk of side effects;
  - Members with diabetes using recommended blood pressure medications;
  - Patients taking oral diabetes medication as directed;
  - Patients taking blood pressure medication as directed; and
  - Patients taking cholesterol medication as directed.
Impact on Pharmacies (cont.)

- Comprehensive Medication Reviews (CMR) completion rate will become a Star rating - currently a display measure.
- In 2012, of the estimated 31 million CMS Part D patients, 9.2% were eligible for a CMR through their PDP.
- Only 11.4% of eligible patients were actually offered an MTM consultation
Display Measures vs Ratings

- In addition to the plan ratings, CMS also uses the “Display Measures” to provide further evaluation of Part D plans.
- The Display Measures are not included in the plan ratings, but are used to facilitate quality improvement by the plans.
- The Display Measures include three PQA-supported measures of medication safety
  - drug-drug interactions;
  - excessive doses of oral diabetes medications;
  - completion rate of Comprehensive Medication Reviews.
- CMS maintains a “Patient Safety website” that provides the benchmarks and scores to the plans across both the Display Measure and Plan Ratings Measures.
Impact on Pharmacies (cont.)

- Barriers to CMRs
  - Time/ resource allocation
  - Return on investment (salary vs. profit)
  - Documentation
  - Patient challenges
Comprehensive Medication Reviews

- The CMR is expected to meet the following professional service definition:
  - A CMR is a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them with the patient, caregiver and/or prescriber.
  - A CMR is an interactive person-to-person or telehealth medication review and consultation conducted in real-time between the patient and/or other authorized individual, such as prescriber or caregiver, and the pharmacist or other qualified provider and is designed to improve patients’ knowledge of their prescriptions, over-the-counter (OTC) medications, herbal therapies and dietary supplements, identify and address problems or concerns that patients may have, and empower patients to self manage their medications and their health conditions.
Comprehensive Medication Reviews (cont.)

- An individualized, written summary in CMS’ standardized format is required to be delivered following each CMR.
  - Over 14% of programs also provide alternative language translations (up from 9.8% in 2013).
- Beyond the required services, sponsors can provide additional value added services (e.g. refill reminders, newsletters)
Comprehensive Medication Reviews (cont.)

- 95.8% of programs offer the interactive, person-to-person CMR consultation via the phone.
- 58.2% of programs also offer face-to-face CMRs (up from 42.4% in 2013).
- 15.9% of programs offer CMRs through telehealth technologies
Impact on Pharmacies (cont.)

- Sponsors can use internal staff, outside personnel or both for delivery of MTM services (multiple selections are allowed).
- In 2014, 45.7% of programs use internal staff (up from 35.4% in 2013), and 88.3% of programs use outside personnel.
- A higher share of PDPs use outside personnel compared to MA-PDs (alone or in combination with internal staff).
Impact on Pharmacies (cont.)

- Outside personnel may include a Prescription Benefit Management (PBM) company, MTM vendor, disease management vendor, community pharmacists, LTC pharmacists, or others
- Wholesalers may provide support
  - Documentation
  - Performance of CMR
  - Communication with patients
- Other resources
  - Consulting companies
- MTM Vendors
Impact on Pharmacies (cont.)

- **EQuIPP** is a performance information management platform that makes unbiased, benchmarked performance data available to both health plans and community pharmacy organizations.

- **EQuIPP** allows pharmacies and pharmacists to better understand the impact they have on patient care by providing user-friendly dashboards of benchmarked performance information, based on accepted standards of quality care.

- Further, the EQuIPP platform allows pharmacists, whether in a large chain community pharmacy organization or an independent community pharmacy, to connect to resources that help them improve.
Collaborative Practice - NY

- A pharmacist who meets the experience requirements and who is employed by or otherwise affiliated with a facility shall be permitted to enter into a written agreement or protocol with a physician authorizing collaborative drug therapy management.

- Collaborative drug therapy management shall mean the performance of services by a pharmacist relating to the review, evaluation and management of drug therapy to a patient, who is being treated by a physician for a specific disease or disease state, in accordance with a written agreement or protocol with a voluntarily participating physician and in accordance with the policies, procedures, and protocols of the facility.
Collaborative Practice NY (cont.)

- Adjusting or managing a drug regimen of a patient, pursuant to a patient specific written order or protocol made by the patient's physician, which may include adjusting drug strength, frequency of administration or route of administration. Adjusting the drug regimen shall not include substituting or selecting a different drug which differs from that initially prescribed by the patient's physician unless such substitution is expressly authorized in the written order or protocol. The pharmacist shall be required to immediately enter into the patient record any change or changes made to the patient's drug therapy and shall use any reasonable means or method established by the facility or the department to notify any of the patient's other treating physicians with whom he or she does not have a written agreement or protocol regarding such changes. The patient's physician may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist;

- Evaluating and, only if specifically authorized by the protocol and only to the extent necessary to discharge the responsibilities set forth in this section, ordering clinical laboratory tests related to the drug therapy management for the specific disease or disease state specified within the protocol; and

- Only if specifically authorized by the protocol and only to the extent necessary to discharge the responsibilities set forth in this section, ordering or performing routine patient monitoring functions as may be necessary in the drug therapy management, including the collecting and reviewing of patient histories, and ordering or checking patient vital signs, including pulse, temperature, blood pressure and respiration.
Collaborative Practice – Scope

- Collaborative drug therapy management may include the collecting, analyzing, and monitoring of patient data, ordering or performing of laboratory tests based on the standing orders of a physician as set forth in the written collaborative practice protocols, consistent with (c) below; ordering of clinical tests based on the standing orders of a physician as set forth in the written collaborative practice protocols; modifying, continuing, or discontinuing drug or device therapy; and therapeutic drug monitoring with appropriate modification to dose, dosage regimen, dosage forms, or route of administration.
Collaborative Practice – NJ (cont.)

- Collaborative Practice – Scope
  - A pharmacist may perform laboratory tests that are granted waived status in accordance with the provisions of the "New Jersey Clinical Laboratory Improvement Act," P.L. 1975, c. 166 (N.J.S.A. 45:9-42.26 et seq.), Department of Health and Senior Services' rules set forth at N.J.A.C. 8:44, and Department of Health and Senior Services CLIA Program requirements, available at http://www.state.nj.us/health/phel/instruct116.shtml, provided the tests are consistent with the pharmacy practice area or disease state covered by the collaborative practice agreement.

  - The interpretation of clinical or laboratory tests under a written collaborative practice protocol shall be performed by a pharmacist only in direct consultation with a physician.
Collaborative Practice – NJ (cont.)

- Collaborative Practice – Scope
  - Collaborative drug therapy management shall not include therapeutic interchange at the time of dispensing without the prior, specific informed consent of the patient and the consent of the patient's physician. Written confirmation of the consent, which may be by electronic means, shall be maintained at the pharmacy practice site of the collaborating pharmacist.
  - Collaborative drug therapy management shall be between a single patient with whom the physician has a bona fide physician-patient relationship, the physician, and the patient's collaborative practice pharmacist(s) and shall address that patient's specific condition, disease or diseases.
What is the future of MTM?

- On May 7, 2014 CMS issued a 2015 Medication Therapy Management (MTM) Program Guidance that included none of the proposed changes that would have substantially expanded the pool of beneficiaries eligible for MTM services.

- “CMS is committed to keeping the Medicare Part D prescription drug benefit successful, with broad beneficiary appeal and costs as low as possible . . . While we are currently reviewing comments on the proposed expansion of the [MTM] provisions in the proposed rule, we wanted to give the Part D sponsors needed guidance in their submission of their 2015 MTM programs.” - Sean Cavanaugh, deputy administrator and director of the Center for Medicare
What is the future of MTM? (cont.)

- The proposed rule, expressed its intent to “improve access” to MTM services by making multiple modifications to previous requirements.
- Specifically, in January 2014 CMS proposed to:
  - Revise its earlier interpretation of “multiple chronic diseases” as a minimum of three chronic diseases (out of the total core nine conditions) to require that plan sponsors target enrollees with at least two chronic diseases, thus broadening the eligible population.
  - Change the “multiple Part D drugs” definition from no more than eight Part D covered drugs to require that plans target beneficiaries taking two or more Part D drugs for MTM services, which also would expand MTM eligibility.
  - Set the annual per patient drug cost threshold at $620, “which is the approximate cost of filling two generic prescriptions,” explained CMS.
  - Combine hypertension and congestive heart failure into one category labeled “cardiovascular disease” to result in a total of eight core chronic diseases.
What is the future of MTM? (cont.)

- November 2014 – CMS issued request for comments regarding “Enhancements to the Star Ratings for 2016 and Beyond”
- Proposed new 2016 Measure re: MTM
- Comments being reviewed
What is the future of MTM? (cont.)

- Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews (Part D).
  - This measure is based on the PQA-endorsed measure, Completion Rate for Comprehensive Medication Review (CMR), which measures the percentage of beneficiaries who met eligibility criteria for the Medication Therapy Management (MTM) program and who received a CMR with a written summary in CMS standardized format.
  - Since this is a first year measure, it will be assigned a weight of “1”; in future years it will continue to receive a weight of “1” as a process measure. The specifications from the 2015 Display Measure will continue to be used for the 2016 Star Rating.
    - The denominator is the number of beneficiaries who were at least 18 years or older as of the beginning of the reporting period and who were enrolled in the MTM program for at least 60 days during the reporting period.
    - Only those beneficiaries that meet the contracts’ specified targeting criteria per CMS – Part D requirements pursuant to §423.153(d) of the regulations at any time in the reporting period are included in this measure.
    - Beneficiaries that were in hospice at any point during the reporting period are excluded.
    - The numerator is the number of beneficiaries included in the denominator who received a CMR at any time during the reporting period.
  - Sponsors are reminded that they should not restrict their MTM eligibility criteria to limit the number and percent of beneficiaries who qualify for these programs and to whom they must offer a CMR.
What is the future of MTM? (cont.)

- Established in 2006, the Pharmacy Quality Alliance (PQA) is a 501(c)3 designated non-profit alliance with over 100 member organizations.
- It is a multi-stakeholder, consensus-based membership organization that collaboratively promotes appropriate medication use and develops strategies for measuring and reporting performance information related to medications.
Other issues

- Liability
- Contracting
- Audits
- Central Fill?
- HIPAA
An employer is liable for the negligence of his employees. For example, the pharmacist could be liable for the negligence of a technician if he had a duty to check his work.

What about an R.Ph. conducting a CMR?
MTM & Joint and Several Liability

Those who act together in committing a wrong, or whose acts if independent of each other, unite in causing a single injury.

Thus, the defendants can be held fully or partially responsible for the entire injury.

What about multiple parties involved in MTM?
MTM & Joint and Several Liability

- Multiple providers
  - Does the pharmacy have a complete profile?
  - Are there competing therapies?
  - Is the message consistent (e.g. R.Ph. vs. MD)?
MTM & Contracting

- New level of contractual language
- PBM may have additional requirements
  - Required actions
  - Document retention
  - Audits
- PSAO’s and collective contracts
Does MTM require Central Fill Agreements?

- Not an issue if conducting in-house
- What about external actors?

- "Drug utilization review" includes, but is not limited to, the following activities . . . Evaluation of prescription drug orders and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.” Id. (emphasis added)
Does MTM require Central Fill Agreements?
(cont.)

- "Pharmacy practice site" means any place in this State where drugs are dispensed or pharmaceutical care is provided by a licensed pharmacist, but shall not include a medical office under the control of a licensed physician.

- “Pharmaceutical care" means the provision by a pharmacist of drug therapy review and other related patient care services intended to achieve positive outcomes related to the treatment, cure or prevention of a disease; control, elimination or reduction of a patient's symptoms; or arresting or slowing of a disease process as defined by the rules and regulations of the board.” NJSA 45:14-41 (emphasis added).
MTM & Business Associates (HIPAA)

- A business associate is a person or organization, other than a member of a covered entity’s workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. These functions or activities include claims processing, data analysis, utilization review, and billing.

- When a covered entity uses a business associate, the Privacy Rule requires that the covered entity create a business associate agreement. The specific requirements to a business associate agreement can be found under 45 C.F.R. 164.504(e).

See 45 C.F.R. 160.103, 45 C.F.R. 164.502(e), 45 C.F.R. 164.504(e)
What’s New - Business Associates

- The HIPAA Privacy and Security Rules permit a covered entity to disclose protected health information to a business associate, and allow a business associate to create, receive, maintain, or transmit protected health information on its behalf, provided the covered entity obtains satisfactory assurances in the form of a contract or other arrangement that the business associate will appropriately safeguard the information.

- The HIPAA Rules define “business associate” generally to mean a person who performs functions or activities on behalf of, or certain services for, a covered entity that involve the use or disclosure of protected health information.
What’s New - Business Associates (cont.)

- New HIPAA Rule adds patient safety activities to the list of functions and activities a person may undertake on behalf of a covered entity that give rise to a business associate relationship.

- Patient Safety Organizations (PSOs) must be treated as business associates when applying the Privacy Rule.
What’s New - Business Associates (cont.)

- New Rule modifies definition of Business Associate to include:
  - A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires routine access to such protected health information; and
  - A person who offers a personal health record to one or more individuals on behalf of a covered entity.
  - Entities that manage the exchange of protected health information through a network, including providing record locator services and performing various oversight and governance functions for electronic health information exchange would fall within the definition of “business associate.”
What’s New - Business Associates (cont.)

- Clarifies the definition of “business associate” to provide that subcontractors of a covered entity, i.e., those persons that perform functions for or provide services to a business associate other than in the capacity as a member of the business associate's workforce, are also business associates to the extent that they require access to protected health information.

- The definition would apply to an agent or other person who acts on behalf of the business associate, even if the business associate has failed to enter into a business associate contract with the person.