STRATEGIC HEALTH LAW

Medicare Advantage Plan-Provider Relationships: Legal and Regulatory Considerations

Emily A. Moseley
Member, Strategic Health Law

Brian Vick
Managing Counsel,
Blue Cross Blue Shield of North Carolina

North Carolina Society of Health Care Attorneys
October 6, 2017

Agenda

- Overview of Medicare Advantage (MA),
  - The MA payment model
  - Required benefits
- Provider Relationships
  - Networks
  - Required contract provisions
  - Value based contracting
  - Coding accuracy and risk adjustment
  - Provider directories and organizational determinations
- Subcontractors or “FDRs”

Medicare Advantage

- 57 million people on Medicare
- 17.6 million enrolled in an MA plan (roughly 31%)
- MA Plans provide:
  - Medicare A & B benefits
  - Supplemental benefits
  - Utilization management, quality improvement, chronic care management programs
- MA Members receive any Part D benefits through combined MA-PD
- Uniformity and non-discrimination

Medicare Advantage Plan Benefits

- Must cover all services covered under Original Medicare
- Can design own benefit structure with co-payments, coinsurance, deductibles or no deductibles
- Must follow National and Local Medicare Coverage Determinations and Coverage Guidelines
- May offer supplemental benefits (e.g., Silver Sneakers, dental, vision)
- Conduct utilization management
- Generally must have quality improvement and chronic care management programs
- Mandated out-of-pocket maximum for year

Laws, Regulations, and Guidance

Key MA and Part D Resources

MA (Part C)

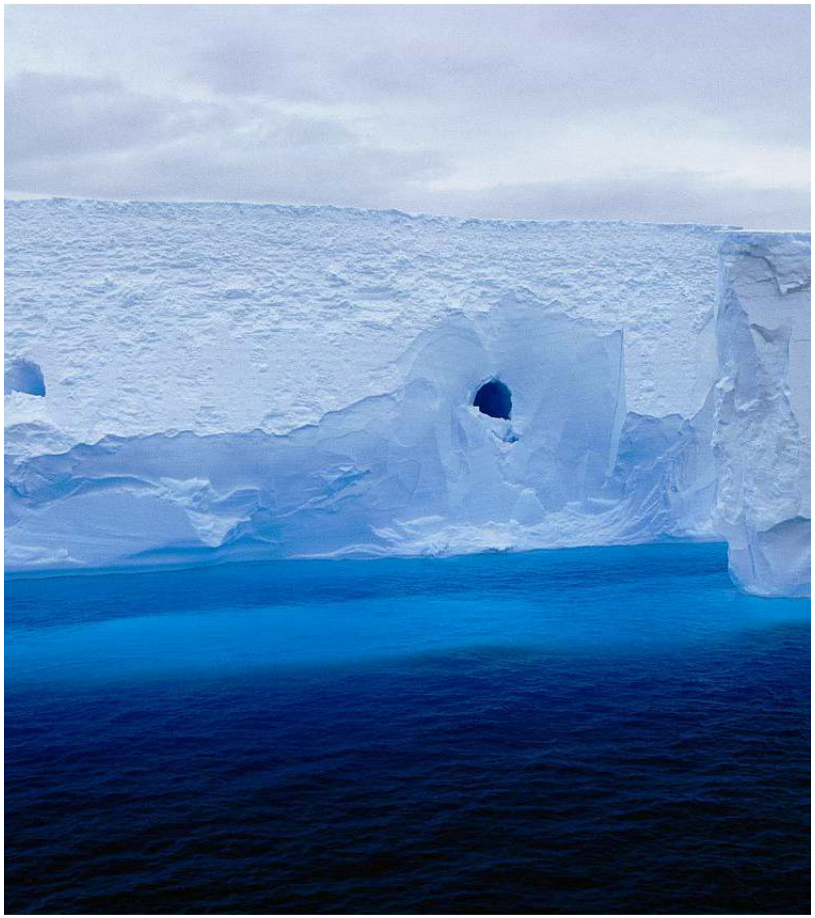
- Title XVIII of the Social Security Act, Part C, §1851, et. seq., 42 U.S.C. § 1395w-21, et seq.
- 42 C.F.R. Part 422
- CMS Medicare Managed Care Manual
- Additional CMS guidance, including HPMS memos sent to plan sponsors

Part D

- Title XVIII of the Social Security Act, Part D, § 1860D-1, et seq., 42 U.S.C. § 1395w101, et. seq.
- 42 C.F.R. Part 423
- CMS Medicare Prescription Drug Benefit Manual
- Additional CMS guidance, including HPMS memos sent to plan sponsors

Regulations Are Just The Tip of The Iceberg

- Voluminous sub-regulatory requirements apply to MA and Part D plans
- Manuals
- HPMS Memos
- Call Letters
- Reporting Requirements



Plans and Providers

Networks, Contracts, and Value Based Insurance Design

Provider Contracts

- "Non-interference clause" – government is not involved in rate negotiations or disputes between MA or Part D plan sponsors and providers
- Rates are the product of private negotiations
- MAOs can:
  - Use different reimbursement amounts for different specialties or for different practitioners, and
  - Implement measures designed to maintain quality and control costs consistent with responsibilities.
- Out of Network Payment Guide – governs payments to non-contracted providers, who are entitled to 100% of Original Medicare reimbursement
- Additional requirements for provider contracts (e.g. prompt pay)

Basic MA Healthcare Provider Contract Requirements

- Beneficiary privacy and confidentiality of health records;
- Prompt pay;
- Hold harmless;
- Compliance with Medicare laws, regulations, and CMS instructions;
- Accountability provisions.

MAO Policies and Procedures

In addition to the provisions mentioned above, MA organizations must include certain MA-related provisions in the policies and procedures that are distributed to providers and suppliers that constitute the organizations' health services delivery network. The following table summarizes these provisions. Access the CFR online.

CONTRACT REQUIREMENTS THROUGH POLICIES, STANDARDS & MANUALS	
Safeguard privacy and maintain records accurately and timely	422.118
Permanent "out of area" members to receive benefits in continuation area	422.54(b)
Prohibition against discrimination based on health status	422.110(a)
Direct access to mammography and influenza vaccinations	422.100(g)(1)
No copy for influenza and pneumococcal vaccines	422.100(g)(2)
Services available 24 hrs/day, 7 days/week	422.112(a)(7)
Adhere to CMS marketing provisions	422.80(a), (b), (c)
Ensure services are provided in a culturally competent	422.112(a)(8)
Pay for renal dialysis for those temporarily out of a service area	422.100(b)(1)(iv)
Provide services in a manner consistent with professionally recognized standards of care	422.504(a)(3)(iii)
Continuation of benefits provisions (may be met in several ways, including contract provision)	422.504(g)(2)(i); 422.504(g)(2)(ii); 422.504(g)(3)

CONTRACT REQUIREMENTS THROUGH POLICIES, STANDARDS & MANUALS	
Payment and incentive arrangements specified	422.208
Subject to applicable Federal laws	422.504(h)
Disclose to CMS all information necessary to (1) Administer & evaluate the program (2) Establish and facilitate a process	422.64(a): 422.504(a)(4) 422.504(f)(2)
Submission of data, medical records and certify completeness and truthfulness	422.310(d)(3)-(4), 422.310(e), 422.504(d)-(e), 422.504(i)(3)-(4),
benefits re: disenrollment rates for beneficiaries enrolled in the plan for the previous two years	
Disclose to CMS quality & performance indicators for the benefits under the plan regarding enrollee satisfaction	422.504(f)(2)(iv)(B)
limited to: Federal criminal law, the False Claims Act (31 U.S.C. 3729 et. Seq.) and the anti-kickback statute (section 1128B(b) of the Act)	
Prohibition of use of excluded practitioners	422.752(a)(8)
Adhere to appeals/grievance procedures	422.562(a)

Medicare Managed Care Manual, Ch. 11 § 100.4

Physician Incentive Plans

- A Physician Incentive Plan is:
  - Any compensation arrangement
  - Between an MA organization and a physician or physician group
  - That may directly or indirectly have the effect of reducing or limiting the services provided to plan enrollees.
- May not directly or indirectly, make any payment as an inducement to reduce or limit the provision of medically necessary services furnished to any particular enrollee.
- If a physician or physician group is placed at *substantial financial risk* for services that the physician or physician group *does not furnish itself*, the MAO must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection.

Substantial Financial Risk

- Does not include payments based on quality of care furnished.
- When risk is based on the use or costs of referral services and exceeds a risk threshold of 25 percent of potential payments ("PP"):
  - Withholds > 25% of PP
  - Withholds < 25% of PP if potentially liable for amounts > 25 % of PP
  - Bonuses > 33 % of PP – bonus
  - Withhold + bonuses if withholds + bonus = more that 25% of PP
  - Capitation arrangements
    - Difference between max and minimum PP is >25% of max PP;
    - Max and minimum PP are not clearly explained in contract.
  - Any other incentive arrangements that have the potential to hold a physician or physician group liable for > 25% of PP.

Value-Based Insurance Design

- Balancing Innovation with Legal Risk
  - Non-Interference Clause
  - Anti Kickback Statute
  - Complex regulations
  - Limitations of CMMI Waivers
- New administration and new direction for CMMI?
  - Proposal to cancel some demonstration pay models and to make others voluntary
  - But possible outcomes-based leukemia drug agreement

VBID Model Test

- Encourage use of high-value clinical services and most cost-effective care
- Eligible enrollees:
  - Determined based on ICD-10 code
  - Diabetes, congestive heart failure, chronic obstructive pulmonary disease ("COPD"), past stroke, hypertension, coronary artery disease, mood disorders, or combinations of these conditions

Announcement of Part D Enhanced Medication Therapy Management Model Test, HMPS Memo (September 28, 2015); 42 C.F.R. §§ 422.2, 422.100(d)(2) & 422.254(b)(2)

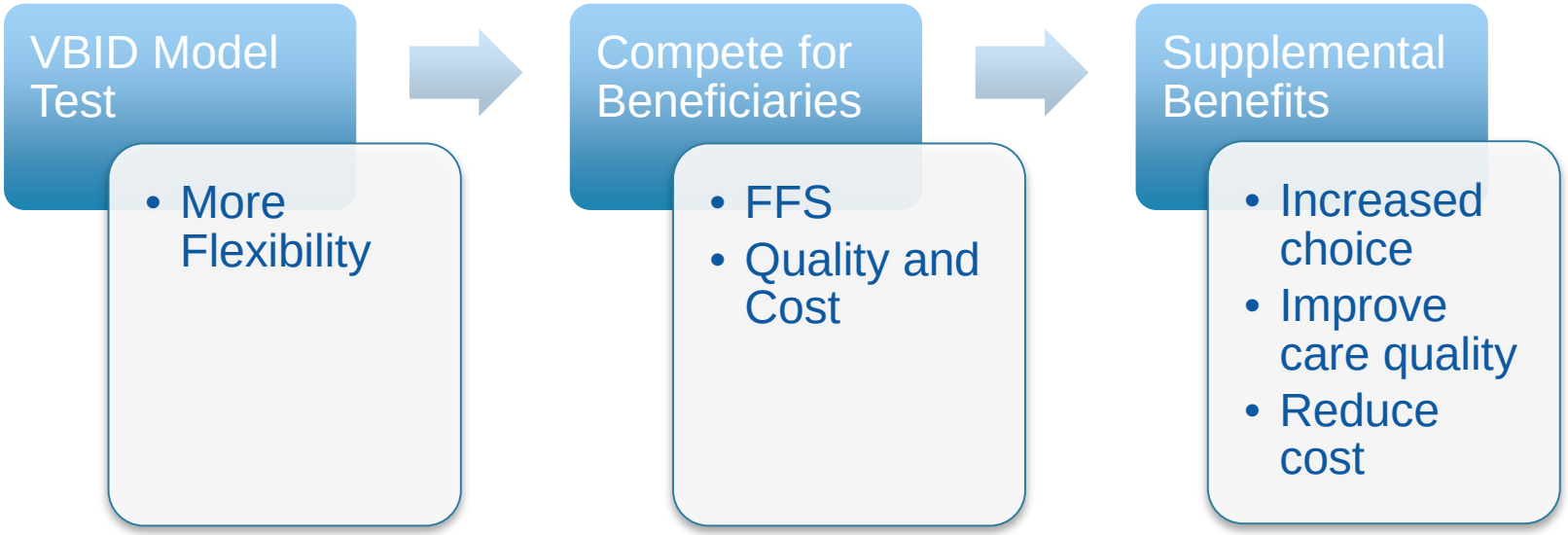
Permissible Interventions

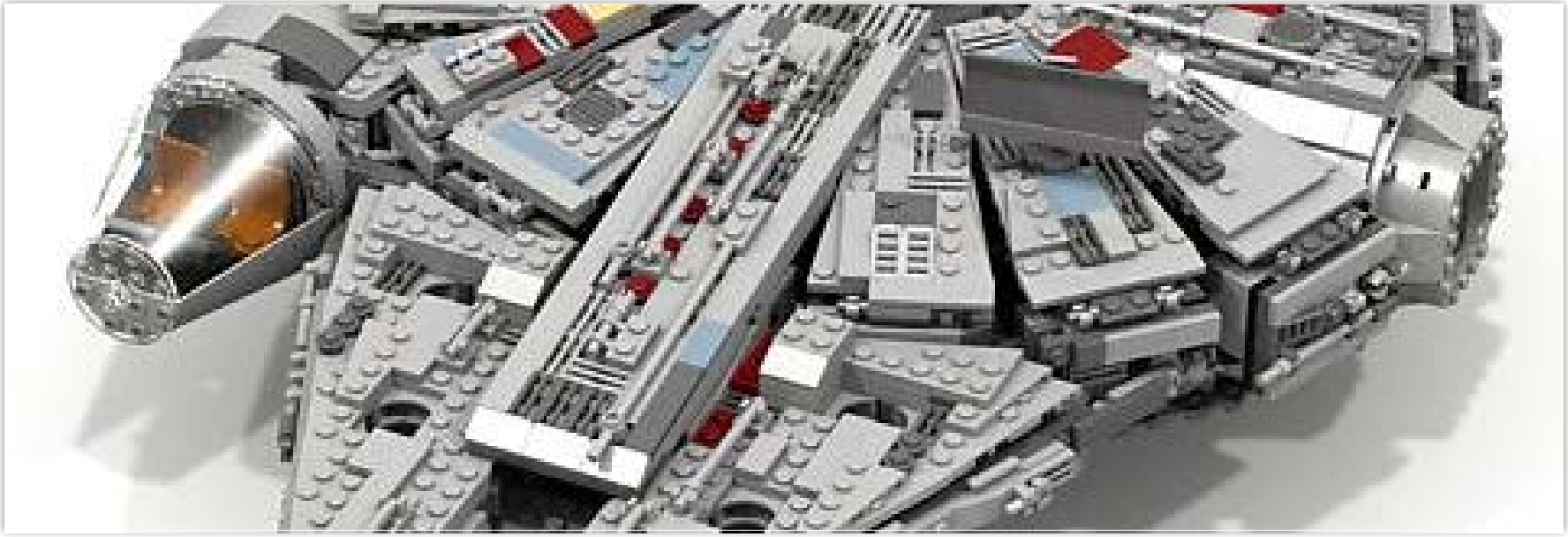
- "Carrots" only:
  - Reduced cost-sharing for high value services;
  - Reduced cost-sharing for high-value providers;
  - Reduced cost-sharing for enrollees participating in disease management or related programs; or
  - Clinically targeted additional supplemental benefits.
- Participation milestones, not clinical goals

September 20th RFI

- Increased Participation in Advanced APMs
- Consumer-Directed Care & Market-Based Innovation
- Physician Specialty
- Prescription Drug
- Medicare Advantage Innovation
- State-Based and Local Innovation (Medicaid)
- Mental and Behavioral Health
- Program Integrity

MA Innovation Models





Coding and Risk Adjustment

Putting the Pieces Together

CMS Payments to MA Plans

- Capitated, per member per month (PMPM)
- Payment = county benchmark x risk score
  - MA benchmark rates set based on each county's per capita FFS (Original Medicare) spending
  - Adjusted by risk score, based on demographic and disease factors
  - Quality Bonus Payments, based on star ratings, added to applicable benchmarks for higher rated plans.
- Plan's aggregate bid amount – benchmark = rebate or member premium

Risk Adjustment Basics

- Risk adjustment process ensures that a plan is properly compensated for the risk that it has assumed for each enrollee
- “Risk” is determined primarily based the diagnosis codes reported by an enrollee’s health care provider
- MA plans must ensure that all risk-related data is accurate, complete, and truthful, including:
  - Enrollment information and encounter data
  - Risk adjustment data
  - Bid data

Risk Scoring Under CMS-HCC Risk Adjustment Model

Demographic Factors

- Age
- Sex
- Disabled status
- Original reason for Medicare entitlement (age or disability)
- Medicaid eligibility
- Institutional status

Disease Factors

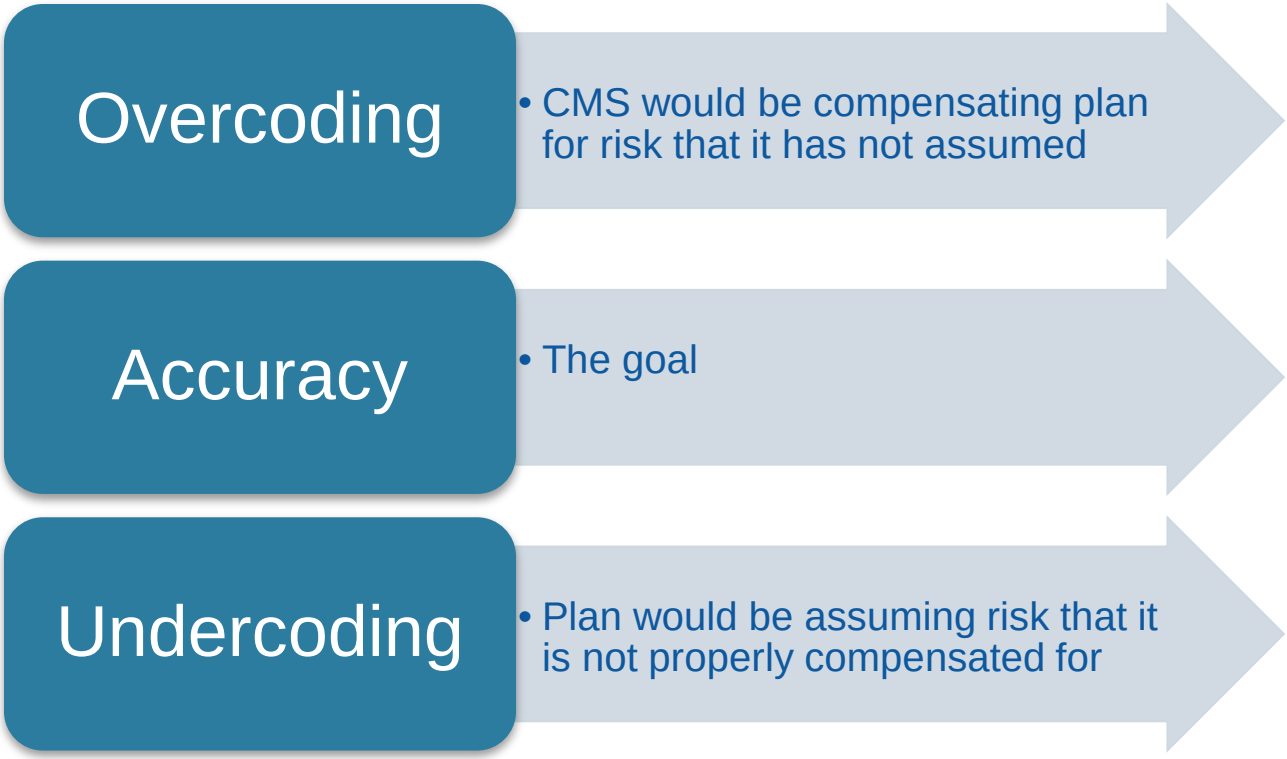
- HCCs specific to each enrollee's diagnoses
- Disease and disabled "interactions"
- "Hierarchical" – counts disease with highest severity in a category:
  - Diabetes without complications (HCC17 = 0.162)
  - Diabetes with Ketoacidosis (HCC 19 – 0.339)

Risk Score Calculation Example

All conditions coded appropriately		Some conditions coded with poor specificity		No conditions coded	
76 year female	0.468	76 year female	0.468	76 year female	0.468
Medicaid eligible	0.177	Medicaid eligible	0.177	Medicaid eligible	0.177
DM w/ vascular CC (HCC 15)	0.608	DM w/o CC (HCC 19)	0.181	DM not coded	
Vascular disease w/CC (HCC 104)	0.645	Vascular disease w/o CC (HCC 105)	0.324	Vascular disease not coded	
CHF (HCC 80)	0.395	CHF not coded		CHF not coded	
Disease Interaction*	0.204	No Disease Interaction		No Disease Interaction	
Total RAF	2.497	Total RAF	1.15	Total RAF	0.645
PMPM Payment	$1,873	PMPM Payment	$863	PMPM Payment	$484
Annual Payment	$22,473	Annual Payment	$10,350	Annual Payment	$5,805

Jonathan Hendrickson, Principal, Consulting Actuary, Milliman, "Medicare Advantage Risk Adjustment and False Claims Liability," October 16, 2015. Used with permission. For illustration only. Dollar amounts are not current.

Focus on Coding Accuracy



Selected Plan Sponsor Obligations Risk Adjustment Accuracy

- Ensure accuracy and integrity of risk adjustment data submitted
- All codes submitted must be documented in medical record as a result of a face-to-face visit and from acceptable data sources
  - Hospital inpatient facilities
  - Hospital outpatient facilities
  - Physicians
  - (Not acceptable examples: Diagnostic Radiology; Skilled Nursing Facility; Freestanding Ambulatory Surgical Center; Home Health Care, Durable Medical Equipment)
- Delete previously submitted codes that do not meet risk adjustment submission requirements
- Inform CMS immediately upon finding that inaccurate data was submitted to CMS

The Dangers of Provider Risk Sharing:

- *U.S. v. Thompson*, Southern District of Florida
- MD had capitated payment arrangement with MA Plans.
  - MD received a percentage of any increase in premiums that resulted from his risk-coding activities
  - MD falsely diagnosed hundreds of patients with a rare disease and received over $1.68 million in payments from plan as a result
- Convicted of criminal health care fraud: (1) 46 months prison time, (2) $2.11 million fine, and (3) exclusion for 25 years
- No allegation that plan was involved in wrongdoing.
- Case highlights
  - The importance of understanding the incentives created by risk-based compensation arrangements with MA plans, and
  - The dangers of percentage of premium compensation arrangements

Call Me:

Plan-Provider Communication

Benefit Coverage Basics

- Organization determinations – plan decisions about the benefits an enrollee is entitled to and the level of cost sharing
- Types of organization determinations
  - Pre-Service request for coverage
    - Standard
    - Expedited (when standard timeframe could jeopardize health)
  - Post-Service request for payment

Medicare Advantage Organization Determinations

- Organization determinations – plan decisions about the benefits an enrollee is entitled to and the level of cost sharing
- Types of organization determinations
  - Pre-Service request for coverage
    - Standard
    - Expedited (when standard timeframe could jeopardize health)
  - Post-Service request for payment

MA Plans and Non-Covered Services

- In Original Medicare, a provider can bill for the full cost of a non-covered service if patient signs an “Advanced Beneficiary Notice” or ABN acknowledging lack of coverage
- ABNs cannot be used with members of MA plans
- MA plans must hold members harmless for the cost of non-covered services unless the member has received a pre-service organization determination denying coverage
- Only exception is where a service is never covered by Medicare under any circumstance
- MA plans often require providers to ensure patient has received a pre-service organization determination for a non-covered service

Timeframes for MA Plan Organization Determinations

Standard Request for Service	• As expeditiously as health condition requires but no later than 14 calendar days
Request for Payment	• Subject to prompt pay requirement of 95% of “clean claims” from members and non-contracted providers paid within 30 days
Expedited Request for Service	• As expeditiously as health condition requires but no later than 72 hours

Reconsiderations and Appeals

- Reconsiderations – first level of appeal of an MA plan's organization determination, handled internally
- If decision on reconsideration adverse to enrollee, plan automatically forwards case to Independent Review Entity (IRE)
- Additional levels of external review available

Timeframes for Reconsiderations

Standard Request for Service Reconsideration	• As expeditiously as health condition requires but no later than 30 calendar days
Request for Payment Reconsideration	• No later than 60 calendar days
Expedited Request for Service Reconsideration	• As expeditiously as health condition requires but no later than 72 hours

External Levels of Appellate Review

Independent Review Entity (IRE)

Administrative Law Judge (ALJ)

Medicare Appeals Council (MAC)

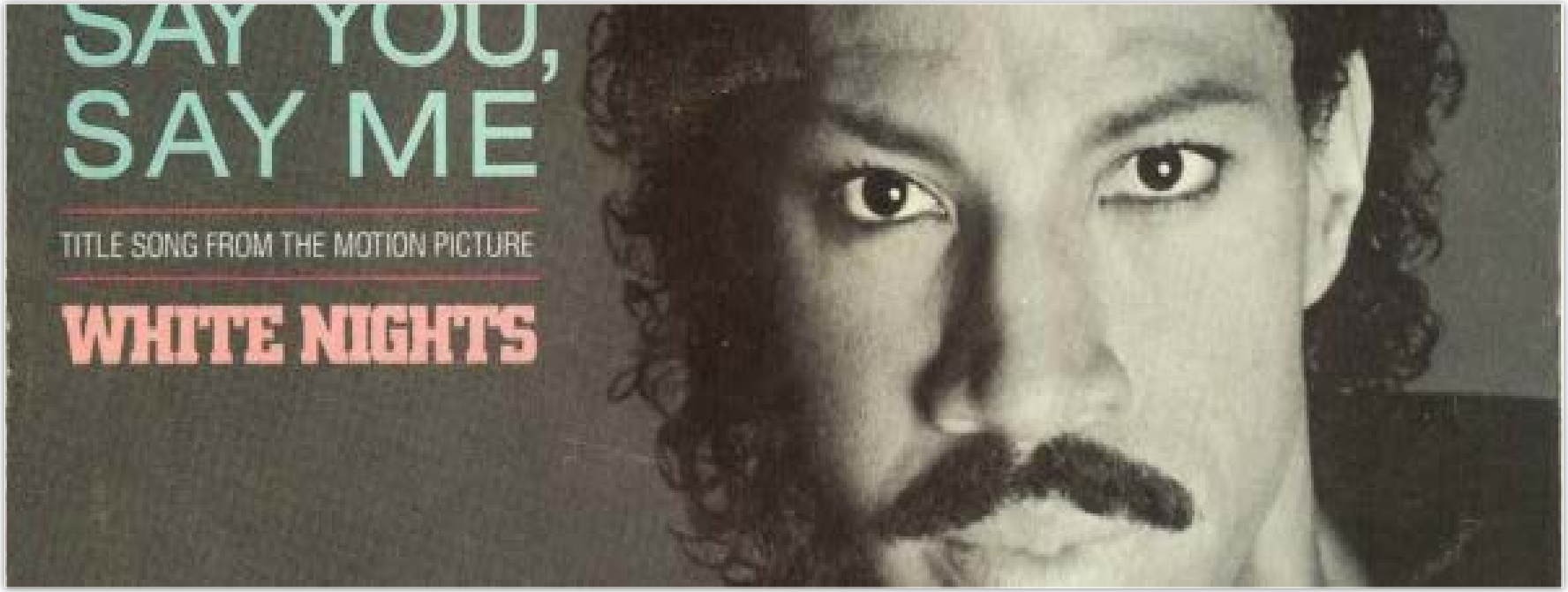
Judicial Review

MA Provider Outreach

	Adjudication Timeframe	Number of Outreach Attempts	Timing of Outreach Attempts
Standard OD Payment	30 days	3	During business hours in the provider's time zone
Standard OD Pre-Service	14 days	3	• Initial attempt within 2 calendar days of receipt of request • When possible, during business hours in the provider's time zone *
Expedited Organization Determinations	72 hours	3	• Initial attempt upon receipt of request • When possible, during business hours in the provider's time zone
Standard Reconsideration	30 days (preservice) 60 days (payment)	3	• Initial attempt within 4 calendar days of receipt of request • When possible, during business hours in the provider's time zone
Expedited Reconsideration	72 hours	3	• Initial attempt upon receipt of request • When possible, during business hours in the provider's time zone

Provider Directories

- Provider Directory Review:
  - 54 plans and 108 provider locations per plan
  - 5,832 providers total: cardiology, oncology, ophthalmology, PCP
- 45.1% of provider directories were inaccurate
  - Percent of inaccurate locations ranged from 1.77% to 86.53%
- Inaccuracies included:
  - Not at the location listed
  - Incorrect phone number was incorrect, or
  - Not accepting new patients
- 52 Plans subjected to Compliance Actions:
  - 30 Notices of Non-Compliance
  - 17 Warning Letters
  - 2 Warning Letters with Request for a Business Plan


SAY YOU,
SAY ME
TITLE SONG FROM THE MOTION PICTURE
WHITE NIGHTS

FDRs

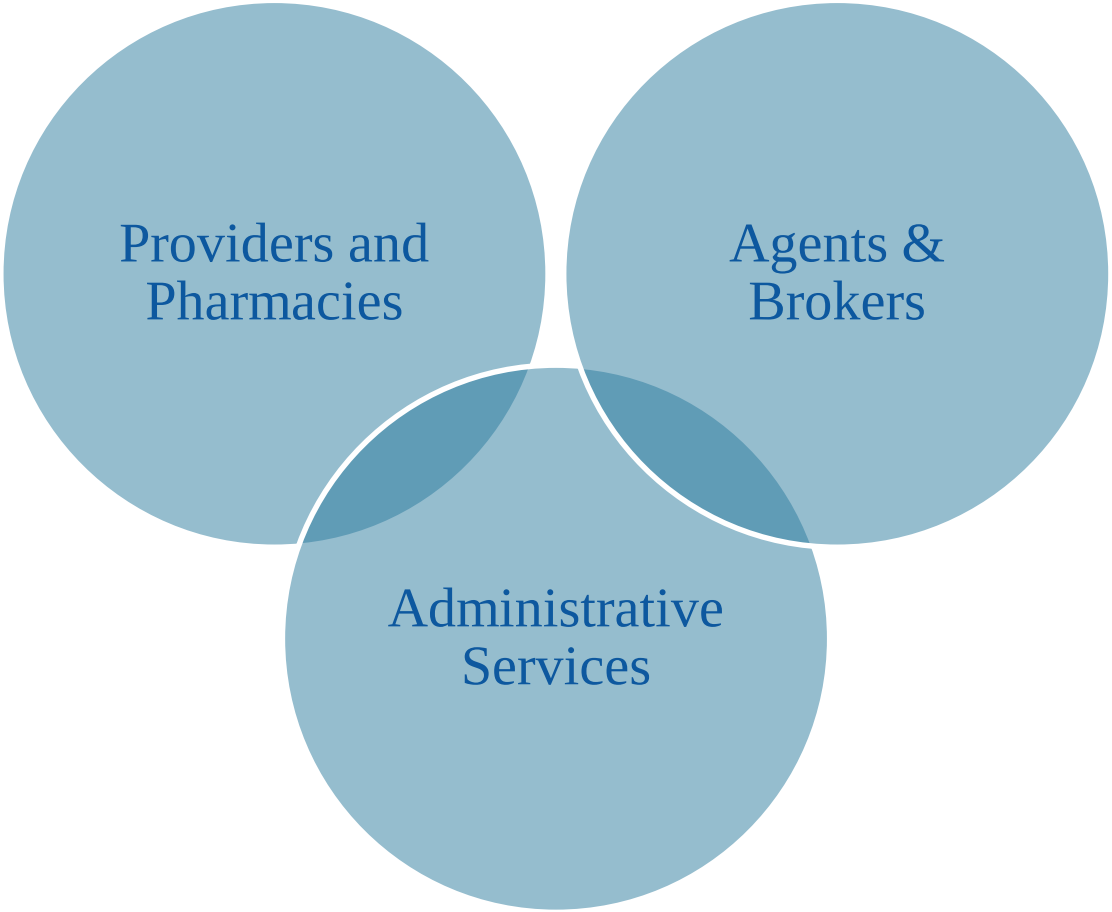
First Tier, Downstream, and Related Entities (FDRs)

- First Tier Entities
  - Any party that enters into a written arrangement, acceptable to CMS, with an MA or Part D plan sponsor or applicant to provide administrative services or healthcare services to a Medicare eligible
- Downstream Entities
  - 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.

First Tier, Downstream, and Related Entities (FDRs) (cont'd)

- Related Entity
  - any entity that is related to an MAO or Part D sponsor by common ownership or control and
    - (1) Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation;
    - (2) Furnishes services to Medicare enrollees under an oral or written agreement; or
    - (3) 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.

FDR Types


Providers and Pharmacies
Agents & Brokers
Administrative Services

Strict Liability for FDRs

- **A plan sponsor has strict liability for the conduct of vendors, known as FDRs, to which the plan has delegated plan administrative services or functions.**
  - FDR = First tier, downstream, and related entities
  - If delegating to FDRs, must list in MA Application
- Examples:
  - Claims administration, processing and coverage adjudication
  - Credentialing
  - Pharmacy benefit management
  - Appeals and grievances

Select FDR Contract Requirements

- **Records** - HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the FDR related to CMS' contract with the Plan Sponsor.
- **Hold Harmless** - Enrollee protection provisions that prohibit providers or pharmacies from holding an enrollee liable for payment of any fees that are the obligation of Plan Sponsor.
- **Flow-Downs** - That any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with Plan Sponsor's contractual obligations.
- **Revocation Rights** - Providing for the revocation of the delegation activities and reporting requirements (or other remedies) if CMS or the Plan Sponsor determines that such parties have not performed satisfactorily.
- **Compliance** - That the FDR must comply with all applicable Medicare laws, regulations, and CMS instructions and the Plan Sponsor's contractual obligations.
- **Ongoing Monitoring** - That the Plan Sponsor will monitor the FDR's performance on an ongoing basis.
- **Prompt Pay** - Prompt payment of clean claims.

Emily A. Moseley
emoseley@strategichealthlaw.com
984.234.0313

Brian Vick
Brian.Vick@bcbsnc.com
919.765.4071