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HHS Final Rule on Accountable Care Organizations (ACO) – Relevant Excerpts

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Overarching aim:

The Department of Health and Human Services Administration/Centers for Medicare and Medicaid Final Rule on Accountable Care Organizations (ACO) (the “Rule”) states that the Medicare Shared Savings Program seeks to achieve a three-part aim that includes the following:

- **better care for individuals**, evidenced in dimensions of safety, effectiveness, patient-centeredness, timeliness, efficiency and equity;
- **better health for populations**, through public health education on causal factors for poor health and the influence of preventative services; and
- **lower growth in Medicare Parts A and B expenditures** [pp. 8, 9]

The Rule identifies the following elements as key to achieving the above “three-part aim”:

- person-centeredness;
- coordination of care;
- attentiveness to care transitions;
- efficiency, waste reduction and a focus on use of internal resources, preventative interventions, diversion from and/or coordinated discharges from hospital care, and avoidance of hospital re-admission;
- prompt and regular communication with patients;
- use of data to improve care delivery and outcomes;
- innovation; and
- staff skill-building.

Goal:

The goal of an ACO is to deliver seamless, high-quality care for Medicare beneficiaries, instead of the fragmented care that often results from a fee-for-service payment system in which different providers receive different, disconnected payments. ACOs will be patient-centered organizations in which the patient and providers are partners in care decisions.

Organizational Structure:

In this context, the term “ACO” refers to a group of providers and suppliers of services (e.g., hospitals, physicians, and others involved in patient care) that will work together to coordinate care for the Medicare fee-for service patients they serve.

Entities that are independently eligible to participate as ACOs include:

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- ACO professionals in group practice arrangements;
- networks of individual practices of ACO professionals;
- partnerships or joint venture arrangements between hospitals and ACO professionals;
- hospitals employing ACO professionals [e.g. physicians, physician assistants, nurse practitioners, or clinical nurse specialists p. 39]; and
- such other groups of providers of services and suppliers as the Secretary determines appropriate [p. 38] – including, under the Rule, Critical Access Hospitals (CAHs) billing under method II, Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs) [pp. 37, 47].

ACOs must be recognized as legal entities.[p. 53] This may be satisfied either by incorporating a new entity or under certain circumstances using an existing incorporation or other organizational structure.[p. 51] ACO structure must include a governing body to provide oversight and strategic direction [p. 65]. ACO structure must also provide an opportunity for meaningful participation by ACO participants and their designated representatives. [p. 61] ACO participants must have at least 75% control of the control of the governing body. [p. 75]

Providers must “be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to [them]” [p. 18], regardless of “noncompliance”. Beneficiaries may decline to participate, and/or may decline on an opt-out basis to permit data sharing of their personal health information. [pp. 19, 185]

An ACO must have assigned to it at least 5,000 Medicare FFS beneficiaries. [p. 21] Only individuals enrolled in original Medicare Parts A & B are permitted to be assigned to an ACO. Individuals who are enrolled in a Part C Medicare Advantage Plan, an organization under section 1876 of the Act, and Programs for All-Inclusive Care (PACE) are not permitted to be assigned to an ACO. [p. 189]

The Rule emphasizes that the Shared Savings Program is voluntary for providers.

“Primary care physicians” include those practicing internal medicine, family practice, general practice and geriatric medicine. [p. 194]

“Primary care services” are defined as HCPCS codes:

- 99201 through 99215
- 99304 through 99340
- 99341 through 99350
- G0402 (Welcome to Medicare visit)
- G0438 and G0439 (annual wellness visits) [p. 193]

The Rule also provides a crosswalk for these codes with revenue center codes used by FQHCs and RHCs [p. 218]:

- 0521 Clinic visit
- 0522 Home visit
- 0524 Visit to member in covered part A stay at SNF
- 0525 Visit to member in SNF (not part A), NF, ICF-MR or other residential facility

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ACO Agreements:

Agreements between CMS and ACOs will be for periods spanning not less than three (3) years. Some may exceed three years. [p. 21] CMS is providing two start dates for cohorts of ACOs that are selected:

- April 1, 2012 (first performance year ending December 31, 2013);
- July 1, 2012 (first performance year ending December 31, 2013). [p. 130]

Among other attestations and aspects of program compliance, the Rule requires ACOs to document plans to:

- promote evidence-based medicine;
- promote beneficiary engagement;
- report internally on quality and cost metrics;
- coordinate care [p. 91]; and
- meet patient-centeredness criteria. [p. 92]

Beneficiary Rights and Assignment:

The Rule emphasizes that participants, all of whom must be enrolled in original, fee-for-service Medicare Parts A & B, “retain all rights and benefits under traditional Medicare” [pp. 14, 244]. This includes the right to see any physician of choice.

“Assignment” does not constitute a lock-in or enrollment [p. 15]. Rather, it will be based on where participants “choose to receive a plurality of their primary care services during the performance year” [pp. 18, 209, 255]. Determination of where a beneficiary has received a plurality of his or her services will follow a “step-wise process”. The “step-wise process” will first examine whether a beneficiary has seen a primary care physician, and if they have, make assignment on that basis. If the analysis reveals that a beneficiary has not seen a primary care physician, the review will move to whether he or she has accessed primary care services from specialists [pp. 202, 210]. The Rule emphasizes that assignment is non-exclusive and that participants can receive services from within and without the ACO [p. 24][generally, see also p. 189].

[Please note change from draft release] Beneficiaries will be assigned based on a preliminary prospective assignment methodology with final retrospective reconciliation based on utilization data demonstrating that the ACO has provided primary care during the performance year. [p. 244]

“Person-Centered”ness:

An ACO will be considered to be “patient centered” if it meets all of these requisites:

- implements a beneficiary experience of care survey and uses the results of same to improve care;
- ensures participant involvement in ACO governance;

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- implements a process for evaluating the health needs of constituent populations, with an emphasis on diversity;
- implements systems to identify high risk individuals, to develop individualized care plans and to integrate community resources;
- provides a mechanism for coordination of care and use of electronic health records (EHR);
- adopts clinical practices through which clinical information is conveyed in a manner that is understandable to beneficiaries, and takes into account individual preferences, values and priorities;
- adopts written standards for beneficiary access and communication, and identifies a process by which beneficiaries can access their medical records; and
- implements internal processes for measuring clinical and service performance by clinicians over time. [p. 93]

Attention to the needs of dual-eligibles:

The Rule identifies “high risk” beneficiaries (including duals, individuals who are entitled to Medicaid by reason of disability and those with diagnoses of mental health or substance abuse disorder p. 546) as an appropriate target for ACOs in that they are likely to benefit from care coordination. The draft release of the Rule conceded that “high-cost beneficiaries are also potentially at-risk for inappropriate avoidance by an ACO because the ACO may believe that it will be more likely to realize shared savings against its benchmark costs if it can avoid having higher-cost patients assigned to it during a performance year.” Addressing this concern, the Rule proposes to require monitoring (e.g. analysis of claims, beneficiary satisfaction surveys, medical records audits) adequate to ensure that ACO’s are not avoiding, preventing access by or reducing services to high risk patients. Where monitoring determines that an ACO has been noncompliant, the Rule proposes to require a corrective action plan, failure to satisfy the terms of which can result in sanctions up to termination as a Sharing Savings Program ACO. [p. 549]

Practice measures:

The Final Rule reduces the number of practice measures by which ACOs will be evaluated from 65 to 33. [p. 327]

These include:

I. Related to the aim of better care for individuals:

- seven measures of patient/caregiver experience [method: survey]:
 - CAHPS: Getting Timely Care, Appointments, and Information
 - CAHPS: How Well Your Doctors Communicate
 - CAHPS: Patients’ Rating of Doctor
 - CAHPS: Access to Specialists
 - CAHPS: Health Promotion and Education
 - CAHPS: Shared Decision Making
 - CAHPS: Health Status/Functional Status

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- six measures of care coordination/patient safety [method unless otherwise indicated: claims]
 - risk standardized, all condition readmission [**Note: pending finalization**]
 - ambulatory sensitive conditions admissions: COPD (AHRQ Prevention Quality Indicator #5)
 - ambulatory sensitive conditions admissions: congestive heart failure (AHRQ Prevention Quality Indicator #8)
 - percent of PCPs who successfully qualify for an EHR Incentive Program Payment [method: EHR Incentive Program Reporting]
 - medication reconciliation: reconciliation after discharge from an inpatient facility [method: GPRO web interface]
 - falls: screening for fall risk [method: GPRO web interface]

II. Related to the aim of better health for populations:

- eight measures related to preventative health [method: GPRO web interface]
 - influenza immunization
 - pneumococcal vaccination
 - adult weight screening and follow-up
 - tobacco use assessment and tobacco cessation intervention
 - depression screening
 - colorectal cancer screening
 - mammography screening
 - proportion of adults age 18+ who had blood pressure measured within preceding 2 years
- six measures related to individuals identified as at risk by reason of diabetes
 - diabetes composite (all or nothing scoring): hemoglobin A1c Control (<8 percent)
 - diabetes composite (all or nothing scoring): low density lipoprotein (<100)
 - diabetes composite (all or nothing scoring): blood pressure <140/90
 - diabetes composite (all or nothing scoring): tobacco non-use
 - diabetes composite (all or nothing scoring): aspirin use
 - diabetes mellitus: hemoglobin A1c poor control (>9 percent)
- one measure related to individuals identified as at risk by reason of hypertension
 - hypertension: blood pressure control
- two measures related to individuals identified as at risk (or frail elderly) by reason of ischemic vascular disease

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- ischemic vascular disease: complete lipid profile and LDL control < 100 mg/dl
- ischemic vascular disease: use of aspirin or another antithrombotic
- one measure related to individuals identified as at risk (or frail elderly) by reason of heart failure
 - heart failure: beta-blocker therapy for left ventricular systolic dysfunction
- two measures related to individuals identified as at risk (or frail elderly) by reason of coronary artery disease
 - coronary artery disease composite (all or nothing scoring): drug therapy for lowering LDL-cholesterol
 - coronary artery disease composite (all or nothing scoring): angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy for patients with CAD and diabetes and/or left ventricular systolic dysfunction

CMS will require a standardized, patient experience of care survey based on CAHPS, and will in 2012 and 2013 pay for administration of such survey for participant ACOs [p. 327]

ACOs must report completely and accurately on all 33 measures for all reporting periods in each performance year. [p. 328] For each measure set/domain, the ACO must report on a random sample consisting of at least 411 assigned beneficiaries [or if less than 411, all beneficiaries]. [p. 336] GPRO web interface will be a primary mechanism for reporting of data, and CMS has agreed to pre-populate the interface with demographic and utilization information for beneficiaries assigned to the ACO [p. 336]

Reporting of quality performance standards will follow the Physician Quality Reporting System but is pending finalization. [p. 540]

Payment Mechanism

"A goal of the Shared Savings Program is to use a portion of the savings (the difference between the ACO's actual expenditures and the benchmark) to encourage and reward participating ACOs for coordinating the care for an assigned beneficiary population in a way that controls the growth in Medicare expenditures for that patient population while also meeting the established quality performance standards." [p. 460]

The model emphasizes "value-based" purchasing that rewards providers for "delivering high quality, efficient clinical care." [p. 8]

Two tracks. After significant review and deliberation, the Rule finalizes two tracks, each of which is associated with the same general program eligibility requirements and methodologies:

- **Track 1 (One-Sided Model):**

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Savings will be calculated using a one-sided shared savings only approach for the duration of an ACO's first agreement period. CMS will then require an ACO that elects to continue in the program to participate under the two-sided model.

Track 2 (Two-Sided Model):

More experienced entities will be authorized to take on more risk and the potential for higher shared savings. [p. 394]

Performance-based eligibility for shared savings. Eligibility for shared savings will be based on whether quality performance standards have been met [p. 343] , based on national benchmarks [p. 346]. The four domains captured above in the Practice Measures section (patient/caregiver experience, care coordination/patient safety, preventative health and at-risk population) will be weighted equally at 25% each. [p. 350] The measure relating to the percentage of PCPs who have qualified for an EHR Incentive Payment will be double weighted [p. 351]

Initially, all measures will be compensated on a pay-for-reporting basis. CMS will transition a portion of the measures from pay-for-reporting to pay-for-performance in the second performance year, and all but one of the remaining measures in the third performance year. [p. 329]

The minimum attainment level for a measure will be a national flat 30% (or where applicable, the national 30th percentile level of performance of FFS or MA quality rates) [p. 352] and CMS will utilize a sliding scale measure scoring approach spanning from 90+ percentile FFS/MA Rate down to 30+ percentile FFS/MA Rate. [p. 357-358]. Improved performance will be rewarded on a scale that yields higher shared savings. [p. 353]

CMS will require ACOs to achieve the quality performance standard on 70% of the measures in each domain. [p. 356] An ACO that fails one or more measures in each domain could still qualify for shared savings if it achieves the overall 70% mark. Notwithstanding, an ACO that scores a zero for an entire measure domain will be disqualified from sharing in any savings. [p. 357] ACOs that fail to correct underperformance through corrective action plans will be terminated. [p. 356]

Calculation of sharing savings. The shared savings rate will be a percent of the difference between estimated average per capita Medicare expenditures under the ACO, adjusted for beneficiary characteristics, and the expenditure benchmark for the ACO. The expenditure benchmark for the ACO will be:

- based on the last three years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries who would have been assigned to the ACO [pp. 419, 436 and 447];
- risk adjusted using the CMS-HCC model [p. 430];
- truncated at the 99th percentile for each benchmark and performance year [p. 420]; and

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- calculated for populations including ESRD, individuals with disabilities, aged/dual eligibles and aged/non-dual eligibles [pp. 420, 436].

IME and DSH payments will be excluded from ACO benchmark and performance year expenditures. [p.441]

The three years of per-beneficiary data will be trended forward using national [p. 454] growth rates in per beneficiary expenditures for Medicare Parts A & B services. [p. 451] The benchmark will be updated during the agreement period by the projected absolute amount of growth in national per capita expenditures for original Medicare FFS Parts A & B [p. 459] and separate cost categories will be calculated for the populations noted earlier in this paragraph. [p. 459] The benchmark will be reset at the start of each agreement period. [p. 419] The shared savings rate will be greater for ACOs that participate in the two-sided model. [p. 401]

The shared savings rate will be subject to a **minimum**:

- for ACOs participating under the **one-sided model**, established using a sliding scale based on the size of the ACO's population [p. 467]; and
- for ACOs participating under the **two-sided model**, a fixed 2 percent [p. 469].

Related, ACOs will be subject to a **cap** on shared savings as follows:

- for those participating under the **one-sided model**, 50% of total savings based on quality performance; and
- for those participating under the **two-sided model**, 60% of those savings. [p. 472]

The Final Rule increases the payment limits proposed under the draft release from 7.5 to 10 percent for ACOs under the one-sided model and from 10 to 15 percent for ACOs under the two-sided model. [p. 492]

The original proposal to implement a 2 percent net sharing rate has been eliminated and now ACOs participating under both the one and two-sided models will be permitted to share on first dollar savings once the minimum savings rate is met or exceeded. [p. 486] In contrast to the draft release, there will be no additional incentives for to ACOs that include an FQHC or RHC as a participant [p. 475] or for serving dual eligibles [p. 481]

CMS will also make available to "eligible professionals" (including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical social workers, clinical psychologists, registered dietitians and nutrition professionals, physical therapists, occupational therapists, qualified speech pathologists and qualified audiologists) as group practices incentive payments related to Physician Quality Reporting System (PQRS). These will be made on a parallel basis with Shared Savings Program reporting and other standards. [p. 369]

Underperforming ACOs may, after receiving a warning, being given an opportunity to re-submit data, and re-evaluation of their subsequent year's performance, be terminated. An ACO that fails to report one or more measures will receive a request to submit. If it fails to meet that requirement or does not provide a reasonable explanation, CMS will immediately terminate its

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agreement. [p. 357] Similarly, ACOs that report inaccurately or incompletely may also be terminated. [pp. 346, 357]

CMS emphasizes that the Medicare program retains both the insurance risk and responsibility for paying claims for services furnished to Medicare beneficiaries, and that potential losses against the benchmark are solely between Medicare and the ACO. [p. 525]

Treatment of shared losses for ACOs participating under the two-sided model. A reciprocal of this method will be used for ACOs participating under the two-sided model that experience loss. [pp. 401, 493] This contemplates a formula for calculating shared losses based on the final sharing rate, use of a minimum loss rate of 2 percent [p. 495] to protect against losses related to random variation, and a loss sharing limit. [p. 493] If an ACO's losses exceed the minimum loss rate, it will be responsible for paying the percentage of excess expenditures on a first dollar basis up to the annual loss limit [p. 495]: 5% in year 1; 7.5% in year 2; 10% in year 3 [p. 498] The loss sharing limit will be one minus the shared savings rate, will apply once the minimum loss rate is met or exceeded, and will be capped at 60%. [p. 496-497]

In the Final Rule, the (self-executing) performance payment withhold that was proposed in the draft release has been eliminated [p. 515] and CMS indicates that it will permit ACOs flexibility in identifying how they will repay potential losses. Notwithstanding, ACOs must repay potential losses equal to at least 1% of total per capita Medicare Parts A & B FFS expenditures for assigned beneficiaries based on either the performance year or the benchmark [p. 509], and will have 90 days within which to make payment in full. [p. 511] If CMS is unable to fully recoup losses from an ACO for a given performance year, it will not carry forward such losses into subsequent performance years and agreement periods. [p. 510]

ACOs with start dates of April 1 and July 1, 2012 will be permitted to seek an interim payment calculation at the end of the first 12 months of program participation. This may yield either shared savings or losses. The procedure for handling savings and losses will parallel what is described above. [p. 521]

Those with net losses in initial agreement period and that apply for continued participation must indicate what caused the loss and identify safeguards to enable achievement of savings. [p. 394]

Prohibition on cross participation/enrichment. ACO participants in the Shared Savings Program are prohibited from also participating in and receiving shared savings from the following:

- Independence at Home
- MHCQ IHIE and NCCCN Demonstrations
- MAPCP arrangements
- PGP Transition Demonstration
- Care Management for High-Cost Beneficiaries Demonstrations
- Pioneer ACO Model through Innovation Center

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CMS will test for duplicative savings earned in another Medicare program or demonstration involving shared savings. [p. 118-119]

Marketing:

ACOs:

- must provide plain language posters and standardized written notices memorializing participation in the Shared Savings Program [p. 531]
- may provide such notices to beneficiaries on their preliminary prospective assignment lists [p. 531]
- are not required to notice participants if the ACO does not renew, or if the ACO's agreement is terminated;
- must conform to requirements concerning marketing materials that include:
 - filing them with CMS 5 days prior to use;
 - using template language, when available;
 - prohibiting discriminatory use;
 - framing them in plain, easily comprehensible language. [p. 537]

Evaluation:

CMS has finalized its intent to use the following mechanisms to evaluate the success of ACOs:

- analysis of financial and quality data;
- site visits;
- collection, assessment and follow-up investigation of beneficiary and provider complaints; and
- audits. [p. 541]

Termination:

CMS is authorized to terminate an ACO based on such factors as avoidance of at-risk beneficiaries and failure to meet quality performance standards. [p. 581]

CMS reserves the right to take the following actions, at its discretion, prior to termination of an ACO for poor quality performance from the SSP:

- issue a warning notice;
- request a corrective action plan [p. 584];
- place the ACO on a monitoring plan.

Alternatively, CMS may immediately terminate an ACO for more serious violations. [p. 551]