Office of the Registrar of Regulations,
Legislative Council,
State of Delaware

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 Delaware Code, Section 512 and 29 Delaware Code, Section 7931
(31 **Del.C.** §512 & 29 **Del.C.** §7931)

FINAL

ORDER

DSSM 80000 Authorization and Regulation of Medicaid/CHIP Accountable Care Organizations

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance initiated proceedings to amend Division of Social Services Manual (DSSM) regarding Accountable Care Organizations, specifically, to set standards for the authorization and regulation for Medicaid/CHIP beneficiaries in the State of Delaware to improve health outcomes while reducing costs. The Department's proceedings to amend its regulations were initiated pursuant to 29 Delaware Code Section 10114 and its authority as prescribed by 31 Delaware Code Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 Delaware Code Section 10115 in the December 2019 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by December 31, 2019 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

Effective for services provided on and after February 11, 2020 Delaware Health and Social Services/Division of Medicaid and Medical Assistance (DHSS/DMMA) proposes to amend section 80000 of Division of Social Services Manual (DSSM) regarding Accountable Care Organizations, specifically, to set standards for the authorization and regulation for Medicaid/CHIP beneficiaries in the State of Delaware to improve health outcomes while reducing costs.

Background

Four years ago, the Centers for Medicare & Medicaid Services (CMS) awarded Delaware a State Innovation Model grant to achieve five state-defined objectives, one of which was to engage payers to move health care payment to a pay-for-value model based on total cost of care budgeting. Since that time, and following considerable intensive stakeholder work, it has become apparent there are limits to the scope and pace of progress through voluntary adoption of payment and delivery reform by payers and providers. In states that have initiated or implemented reform, state government and stakeholders have collaborated to create mechanisms that bolster and accelerate system transformation.

In its 2017 Report to the Delaware General Assembly on Establishing a Health Care Benchmark, DHSS identified five strategies to advance the adoption of value-based payment (VBP) models, one of which was the implementation of total cost of care alternative payment models within Medicaid managed care contracts and the State Employee Benefit Contracts. In 2018, DHSS increased its focus on alternative payment strategies by adding VBP requirements to its Medicaid managed care contracts for calendar year 2018. Furthermore, in 2019, DHSS released a request for information on the design and development of Medicaid Accountable Care Organizations (ACOs) in Delaware.

In an effort to improve health outcomes for Medicaid patients, lower health care costs, and increase provider accountability for quality and cost, Delaware DHSS is now creating a Medicaid ACO program in which ACOs will work with Medicaid managed care organizations (MCOs) as part of their network providers. An ACO is a group arrangement in which health care practitioners (e.g., hospitals, physicians, and other health care providers) agree to assume responsibility for the quality, outcomes and cost of health care for a designated group of Medicaid and/or CHIP beneficiaries.

Statutory Authority

- 42 CFR 438.6(c)(i)
- 29 **Del.C.** §7931(c)

Purpose

The purpose of these regulations is to set forth standards for the authorization and regulation of ACOs for Medicaid/CHIP beneficiaries in the State of Delaware to improve health outcomes while reducing costs.

Public Notice

In accordance with the *federal* public notice requirements established at Section 1902(a)(13)(A) of the Social Security Act and 42 CFR 447.205 and the *state* public notice requirements of Title 29, Chapter 101 of the Delaware Code, Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) gives public notice and provides

an open comment period for thirty (30) days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments were to have been received by 4:30 p.m. on December 31, 2019.

Provider Manuals and Communications Update

A newsletter system is utilized to distribute new or revised manual material and to provide any other pertinent information regarding manual updates. Updates are available on the Delaware Medical Assistance Portal website: https://medicaid.dhss.delaware.gov/provider

Fiscal Impact Statement

ACOs will be required to contract with MCOs; will not be contracting with DHSS. DHSS only reviews and authorizes them to contract with the MCOs.

Summary of Comments Received with Agency Response and Explanation of Changes

The following summarized comments were received:

Comment: Two commenters questioned the impact of subsections 4.1.2. and 4.1.3 and the range of services for which the ACO will be responsible as well as the requirement to have a plan to support care coordination. They questioned if the ACO would be responsible to provide services to Medicaid/CHIP beneficiaries outside of what is included in the Medicaid benefits package, unless there is funding to support social services or recognition of such services as medical or other expense.

Agency Response: ACOs will not be required to provide services to Medicaid/CHIP beneficiaries outside of what is included in the Medicaid benefits package, nor will these services be included in total cost of care calculations. However, ACOs will be required to support care coordination, including to address health-related social needs, and identifying/screening for social needs and providing referrals to communications is one strategy to pursue this goal. However, it is only one strategy, as ACOs may voluntarily decide to provide such services or arrange for such services to be provided as part of a strategy to improve quality and/or lower costs. DMMA plans to elaborate on ACO requirements related to identifying and addressing health-related social needs in the forthcoming ACO Application. Through this Application, ACOs will need to demonstrate experience, ability and skill to perform these types of functions to gain approval status. Then the approved ACOs will need to negotiate agreements with Medicaid managed care organizations (MMCOs) for specific activities.

Comment: One commenter was concerned that subsection 4.1.7, which allows for "any additional requirements" that the agency deems necessary, is an open-ended option to include new requirements and should be eliminated, as there are no specifics to comment upon, and potential ACOs need the assurance that the regulatory process is transparent.

Agency Response: DMMA will keep this language in the regulation and provide additional program guidance in the forthcoming ACO Application. DMMA considers it essential for the success of the Medicaid ACO Program that requirements may need to be updated from time to time to ensure that Medicaid/CHIP beneficiaries served by Medicaid ACOs are receiving high quality, cost-effective care.

DMMA recognizes that many Delaware payers and providers have negotiated, or are negotiating, value-based contracts for Medicaid and intend the ACO program to advance efforts toward value-based payment. This regulation is specific to entities that voluntarily apply to DHSS for authorization and are subsequently recognized as authorized ACOs. The Medicaid ACO Program will not preclude provider organizations that are not participating in the Medicaid ACO Program from entering into value-based payment arrangements with financial risk with MMCOs.

Comment: One commenter questioned if the regulation applies to providers, such as health systems and their employed providers, or to other CINs or ACOs seeking to assume financial risk with Medicaid beneficiaries independent of this ACO process.

Agency Response: This regulation is specific to entities that voluntarily apply to DHSS for authorization and are subsequently recognized as authorized Medicaid ACOs. The Medicaid ACO program will not preclude provider organizations that are not participating in the Medicaid ACO program from entering into other value-based payment arrangements with financial risk with MMCOs.

Comment: Several commenters raised questions about the frequently ACOs will need to seek certification, ACO compliance with certification and clarity around refusal to certify ACOs or withdraw of certification.

Agency Response: Through this regulation, DMMA will approve ACOs to have the opportunity to enter into contract(s) with Medicaid Managed Care Organizations (MMCOs). DMMA's ACO approval will not be explicitly time limited. Approved ACOs can continue to perform as an ACO until the entity no longer satisfies the applicable requirements. "Recertification" is not required at this time, but if DMMA changes approval requirements in the future, ACOs will need to meet those requirements or potentially lose approval status.

Comment: A few commenters suggested that ACO contracts be made available for public comment sufficiently in advance before they are adopted.

Agency Response: DMMA-approved ACOs will have an opportunity to enter into contract(s) with MMCOs. Specific details of the subsequent contract(s) will be negotiated between the MMCOs and ACOs. This regulation does not change existing Delaware policy or regulation concerning how agreements between MMCOs and third-party entities are handled (e.g., MMCO provider/vendor agreements are not subject to public comment).

Comment: A few commenters suggested that ACOs share, for public comment, how it plans to achieve and distribute cost savings and payments, as these plans have implications for patient care. For example, plans should not penalize providers for treating patients with complex conditions that result in higher costs.

Agency Response: DMMA-approved ACOs will have an opportunity to enter into contract(s) with the MMCOs. Specific details of those subsequent contract(s) will be negotiated between the MMCOs and ACOs. This regulation does not change existing Delaware policy or regulation concerning how agreements between MMCOs and third party entities are handled (e.g., MMCO provider/vendor agreements are not subject to public comment).

Comment: A few commenters suggested that the data that ACOs compile should be reported publicly on an annual basis.

Agency Response: DMMA is not intending to require approved ACOs to post data publicly at this time, but will take this suggestion into consideration.

Comment: Several commenters suggest that ACOs should be required to capture, track and report on quality and care measures and share both clinical and administrative data to allow for transparency and integration.

Agency Response: DMMA agrees that Medicaid ACOs must be able to share data, as well as capture, track, and report on quality metrics to successfully achieve the goals of the Medicaid ACO program. The proposed regulation specifies that each ACO seeking authorization must be able to support care coordination across the continuum of care, and have a plan in place to monitor, report, and improve health outcomes and quality. DMMA believes that data sharing and quality reporting are essential elements of demonstrating these needed capabilities. DMMA will require that the MMCOs incorporate a limited number of appropriate quality measures (e.g., Common Scorecard, Statewide benchmarks, etc.) in their agreements with approved ACOs.

Comment: One commenter recommend a revision of subsection 4.1.4. The subsection requires an electronic health record (EHR) and capabilities to exchange data with payers and DHSS, as well as other designated entities such as the Delaware Health Information Network (DHIN). Because CINs or ACOs may include providers using different EHR systems, the commenter suggested the regulation include:

- language that clarifies electronic health records as plural;
- language that specifies that different EHR systems are acceptable, as long as the data can be exchanged; and
- language that exchanges need to be in accordance with widely- adopted industry standards.

Agency Response: DMMA has edited section 4.1.4 to make “electronic health record” plural. DMMA will also consider adding additional clarifications regarding EHRs and data exchange requirements in forthcoming ACO Requirements.

Comment: One commenter urged DMMA to ensure the standards used to authorize Medicaid/CHIP ACOs allow enough flexibility so as not to undermine the tremendous investments, progress and success of the value-based payment models in which Delaware hospitals participate.

Agency Response: DMMA intends to provide flexibility where practical and within the framework developed by the State. DMMA believes the goals of this initiative are consistent with additional progress being undertaken within the State to promote a stronger value-based health care delivery system.

Comment: Several commenters indicated that ACOs should submit gainsharing or shared savings plans for approval, the agency should prohibit plans that result in financial incentives to reduce or limit medically necessary care.

Agency Response: Agreements negotiated between approved ACOs and MMCOs will be subject to DMMA review and approval. The State expects those agreements to have details regarding payments/financial transactions for DMMA to ensure the goals of this ACO initiative are being addressed.

Comment: One commenter requested that DHSS develop a provision that requires payers to provide at least two years of historical claims data to approved ACOs in preparation to take risk.

Agency Response: DMMA recognizes that data sharing and reporting is an important aspect of a successful ACO program and will take this comment into consideration.

Comment: One commenter requested that Independent Practice APRNs be included in the Definitions section (2.0), as well as ensure the arrangements and standards developed by DHHS as noted in 2.0 Definitions section specify eligibility of Independent APRNs to establish and manage ACOs.

Agency Response: DMMA will further define Medicaid ACO participants, including providers eligible to be participating primary care providers, in the forthcoming ACO Application that will be released following the finalization of this regulation. The forthcoming Application will also provide additional clarification and requirements related to the ACO program attribution methodology. DMMA will take this comment into consideration as it formulates the ACO Application.

Comment: One commenter suggested a revision of subsection 4.1.1 which states that an ACO must have “an organizational /governance structure that will have sufficient authority to ensure the delivery of high quality, cost-effective care to Medicaid/CHIP beneficiaries, as determined by DHSS.” The commenter recommend substituting “Medicaid/CHIP beneficiaries it serves.”

Agency Response: DMMA has modified the regulatory language as follows: “The ACO has an organizational/ governance structure that will have sufficient authority to ensure the delivery of high quality, cost-effective care to its attributed Medicaid/CHIP members, as determined by DHSS.”

Comment: One commenter requested that DMMA set parameters around the medical loss ratio target so the risk and

reward are appropriately transferred to the ACO.

Agency Response: DMMA will take this comment into consideration.

Comment: A few commenters recommended a revision of subsection 4.1.5, which states that ACOs must have plans in place to monitor, report, and improve patient health outcomes and quality. These plans should include a mechanism for capturing and incorporating patient feedback in measuring outcomes and quality of care.

Agency Response: DMMA agrees with the intent of this comment. The pending ACO Application will include requirements on the ACO to demonstrate to DMMA how input/feedback from attributed members, families, and providers will be incorporated into the ACO's operations.

Comment: Two commenters suggested that ACOs be obligated to inform the public and gather input about their objectives and strategies, including how they plan to improve health outcomes and care quality/coordination.

Agency Response: The pending ACO Application will include requirements on the ACO to demonstrate to DMMA how input/feedback from attributed members, families, and providers will be incorporated into the ACO's operations. DMMA is not currently envisioning a public information gathering/sharing requirement on the ACOs, but will not preclude that as an option for ACOs and their partner MMCOs to consider.

Comment: Several commenters suggested revisions of the regulation to include more information about DHSS' initial authorization and ongoing oversight of ACOs.

Agency Response: DMMA will not be holding a direct contract with an ACO. Therefore, DMMA will utilize its monitoring and oversight responsibilities of the MMCO program to monitor ACO performance.

DMMA is pleased to provide the opportunity to receive public comments and greatly appreciates the thoughtful input given by:

- Christiana Care Health System
- Community Legal Aid Society, Inc
- Delaware Children's Health Network
- Delaware Coalition of Nursing Practitioners
- Delaware Healthcare Association
- Governor's Advisory Council for Exceptional Citizens (GACEC)
- Highmark BCBSD Health Options Inc.
- State Council for Persons with Disabilities (SCPD)

FINDINGS OF FACT:

The Department finds the proposed changes as set forth in the December 2019 *Register of Regulations* should be adopted with additions. The Department finds that the proposed does not require further public notice or comment under the APA because the amendments are non-substantive pursuant to 29 **Del.C.** §10118(c).

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Division of Social Services Manual (DSSM) regarding Accountable Care Organizations, specifically, to set standards for the authorization and regulation for Medicaid/CHIP beneficiaries in the State of Delaware to improve health outcomes while reducing costs, is adopted and shall be final effective February 11, 2020.

1/14/2020
Date of Signature

Kara Odom Walker, MD, MPH, MSHS,
Secretary, DHSS

80000 Authorization and Regulation of Medicaid/CHIP Accountable Care Organizations

1.0 Authority and Purpose

1.1 This regulation is promulgated pursuant to Section 7931(e) of Title 29, Delaware Code.

1.2 Pursuant to 42 CFR 438.6(c)(1), states may require a Medicaid Managed Care Organization (MMCO) to implement value-based purchasing (VBP) models for provider reimbursement and to participate in Medicaid-specific delivery system reform initiatives.

1.3 Pursuant to 29 **Del.C.** §7931(c), the Division of Medicaid and Medical Assistance ("DMMA"), which is under the direction and control of the Secretary of the Department of Health and Social Services ("DHSS"), is responsible for the performance of all of the powers, duties, and functions specifically related to Medicaid. This includes regulation and administration of MMCO activity, such as contracting with Accountable Care Organizations (ACOs).

1.4 The purpose of these regulations is to set forth standards for the authorization and regulation of ACOs for Medicaid/CHIP beneficiaries in the State of Delaware to improve health outcomes while reducing costs through VBP arrangements which include downside financial risk for participating ACOs.

2.0 Definitions

"**Accountable Care Organization**" or "**ACO**" means a group arrangement in which health care practitioners (e.g., hospitals, physicians, other health care providers) agree to assume responsibility for the quality, outcomes and cost of health care for a designated group of Medicaid and/or CHIP beneficiaries.

"**ACO Contract**" means a contract formed between an ACO and an MMCO that includes payment via a value-based purchasing arrangement as defined by DHSS.

"**ACO Requirements**" means standards developed by DHSS outlining the qualifications needed for an ACO to participate in the program.

"**Value-Based Purchasing**" or "**VBP**" means a model for provider reimbursement that promotes value over volume, such as a shared savings or risk-based arrangement.

3.0 Formation and Existence

3.1 Each ACO seeking approval from DHSS shall demonstrate to the satisfaction of DHSS that:

3.1.1 The ACO is duly formed and validly existing under the laws of the State of Delaware.

3.1.2 The ACO has the necessary corporate or company power to perform its obligations under the ACO Requirements and to enter into ACO Contracts with MMCOs.

3.1.3 The ACO has taken all necessary corporate or company action to authorize the execution, delivery, and performance of ACO Contracts.

3.1.4 The execution and delivery of ACO Contracts, and the performance of the ACO's obligations under the ACO Contract, will not result in a violation of any provision of the ACO's certificate of incorporation, bylaws, or other governing instrument or document whether at the State or Federal level.

4.0 Duties and Obligations

4.1 Each ACO seeking approval from DHSS shall demonstrate to the satisfaction of DHSS that:

4.1.1 The ACO has an organizational/governance structure that will have sufficient authority to ensure the delivery of high quality, cost-effective care to **[its attributed]** Medicaid/CHIP **[~~beneficiaries~~ members]**, as determined by DHSS.

4.1.2 The ACO has demonstrated the capability to offer a comprehensive array of coordinated primary care services, specialty care services, and the ability to provide access, either directly or through affiliations/ contractual relationships, to behavioral health, acute care, community and social support, long term care, and oral health providers, and other organizations as determined by DHSS or as required in the ACO Contract.

4.1.3 The ACO has a plan to support care coordination across the continuum of care, including services that address health-related social needs, within and outside the ACO.

4.1.4 The ACO has an electronic health **[~~record~~ records]** ("EHR") system in place and has the capability to exchange data with MMCOs and DHSS, and other designated entities such as the Delaware Health Information Network (DHIN).

4.1.5 The ACO has a plan in place to monitor, report, and improve patient health outcomes and quality.

4.1.6 The ACO attests that it will not limit beneficiary provider choice and access to providers that are outside the ACO.

4.1.7 Any additional requirements that DHSS determines necessary to meet the goals of improving health outcomes and patient experience, while reducing costs.

5.0 Authorization

5.1 If upon completion of its application, DHSS finds that the ACO has met the requirements therefor under this regulation, DHSS shall authorize the ACO to enter into an ACO Contract with the Delaware MMCOs for purposes of the Delaware Medicaid/CHIP managed care program.

5.2 DHSS's authorization of an ACO shall be limited to the ACO's business related to the Delaware Medicaid/ CHIP managed care program and shall not authorize the ACO to conduct business that would otherwise require licensure under Title 18 of the Delaware Code.

5.3 The ACO shall at all times comply with the requirements set forth under this regulation. DHSS may immediately revoke the ACO's authorization in accordance with its policies or as a result of a breach thereof by the ACO, or upon the determination of DHSS that the ACO is no longer able to meet the duties and obligations