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State/Territory Name: Delaware

State Plan Amendments (SPA) #: DE-19-0004

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-01-16
Baltimore, MD 21244-1850



Children and Adults Health Programs Group

AUG 29 2019

Stephen M. Groff
Director
Division of Medicaid and Medical Assistance
Designee for Rita M. Landgraf, Secretary
Delaware Health and Social Services
P.O. Box 906
New Castle, DE 19720-0906

Dear Mr. Groff:

I am pleased to inform you that your title XXI Children's Health Insurance Program (CHIP) state plan amendment (SPA), DE-19-0004, has been approved. DE-19-0004 demonstrates compliance with the CHIP managed care regulations at 42 CFR 457, Subpart L for utilization of a managed care delivery system. This SPA has an effective date of July 1, 2018.

Sections 2101(a), 2103(f)(3), 2107(b), and 2107(e) of the Social Security Act, as implemented through regulations at 42 CFR 457 Subpart L, describe the application of managed care requirements to CHIP. Delaware has provided the necessary assurances indicating that the state complies with the managed care requirements in the delivery of CHIP services and benefits covered under the state's separate child health plan as of July 1, 2018.

This SPA approval does not substitute for CMS review of any contracts between the state and managed care entities that serve the state's CHIP populations. All managed care contracts for CHIP populations in effect as of the state fiscal year beginning on or after July 1, 2018 must comply with the CHIP managed care regulations and be submitted for CMS review.

Your title XXI project officer is Ticia Jones. She is available to answer questions concerning this amendment and other CHIP-related issues. Her contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
7500 Security Blvd., Mail Stop: S2-01-16
Baltimore, MD 21244-1850
Telephone: (410) 786-8145
E-mail: Ticia.Jones@cms.hhs.gov

Official communication regarding program matters should be submitted simultaneously to Ticia Jones and Francis McCullough, Director, Division of Medicaid Field Operations East. Francis McCullough's contact information is as follows:

Centers for Medicare & Medicaid Services
Division of Medicaid Field Operations East
JFK Federal Building, Suite 2325
Boston, MA 02203-0003

We look forward to continuing to work with you and your staff.

Sincerely,

/signed Anne Marie Costello/

Anne Marie Costello
Director

cc: Francis McCullough, Director, Division of Medicaid Field Operations East

Section 3. Methods of Delivery and Utilization Controls

- Check here if the State elects to use funds provided under Title XXI only to provide expanded eligibility under the State’s Medicaid plan, and continue on to Section 4 (Eligibility Standards and Methodology).

Guidance: In Section 3.1, describe all delivery methods the State will use to provide services to enrollees, including: (1) contracts with managed care organizations (MCO), prepaid inpatient health plans (PIHP), prepaid ambulatory health plans (PAHP), primary care case management entities (PCCM entities), and primary care case managers (PCCM); (2) contracts with indemnity health insurance plans; (3) fee-for-service (FFS) paid by the State to health care providers; and (4) any other arrangements for health care delivery. The State should describe any variations based upon geography and by population (including the conception to birth population). States must submit the managed care contract(s) to CMS’ Regional Office for review.

3.1. Delivery Standards (Section 2102(a)(4)) (42 CFR 457.490; Part 457, Subpart L)

3.1.1 Choice of Delivery System

3.1.1.1 Does the State use a managed care delivery system for its CHIP populations? Managed care entities include MCOs, PIHPs, PAHPs, PCCM entities and PCCMs as defined in 42 CFR 457.10. Please check the box and answer the questions below that apply to your State.

- No, the State does not use a managed care delivery system for any CHIP populations.
- Yes, the State uses a managed care delivery system for all CHIP populations.

The Delaware Healthy Children Program (DHCP) is targeted to children under age 19 with income at or below 212% of the Federal Poverty Level (FPL). There are no variances in service delivery or benefits based upon geography or population. The majority of services are provided by the same fully capitated managed care organizations (MCOs) serving Delaware’s Medicaid population. Children are eligible under Title XXI (DHCP) only after enrollment with a MCO. In addition, there are some benefits provided fee-for-service (FFS).

- Yes, the State uses a managed care delivery system; however, only some of the CHIP population is included in the managed care delivery system and some of the CHIP population is included in a fee-for-service system.

If the State uses a managed care delivery system for only some of its CHIP populations and a fee-for-service system for some of its CHIP populations, please describe which populations are, and which are not, included in the State’s managed care delivery system for CHIP. States will be asked to specify which managed care entities are used by the State in its managed care delivery system below in Section 3.1.2.

Guidance: Utilization control systems are those administrative mechanisms that are designed to ensure that enrollees receiving health care services under the State plan receive only appropriate and medically necessary health care consistent with the benefit package.

Examples of utilization control systems include, but are not limited to: requirements for referrals to specialty care; requirements that clinicians use clinical practice guidelines; or demand management systems (e.g., use of an 800 number for after-hours and urgent care). In addition, the State should describe its plans for review, coordination, and implementation of utilization controls, addressing both procedures and State developed standards for review, in order to assure that necessary care is delivered in a cost-effective and efficient manner. (42 CFR 457.490(b))

If the State does not use a managed care delivery system for any or some of its CHIP populations, describe the methods of delivery of the child health assistance using Title XXI funds to targeted low-income children. Include a description of:

- The methods for assuring delivery of the insurance products and delivery of health care services covered by such products to the enrollees, including any variations. (Section 2102(a)(4); 42 CFR 457.490(a))
- The utilization control systems designed to ensure that enrollees receiving health care services under the State plan receive only appropriate and medically necessary health care consistent with the benefit package described in the approved State plan. (Section 2102(a)(4); 42 CFR 457.490(b))

Guidance: Only States that use a managed care delivery system for all or some CHIP populations need to answer the remaining questions under Section 3 (starting with 3.1.1.2). If the State uses a managed care delivery system for only some of its CHIP population, the State's responses to the following questions will only apply to those populations.

3.1.1.2 Do any of your CHIP populations that receive services through a managed care delivery system receive any services outside of a managed care delivery system?

- No
 Yes

If yes, please describe which services are carved out of your managed care delivery system and how the State provides these services to an enrollee, such as through fee-for-service. Examples of carved out services may include transportation and dental, among others.

Carved out services are:

Similarly to the Medicaid population, children in DHCP receive all medically necessary mental health and substance abuse treatment services (for any treatment modality). Services which exceed the basic MCO benefit of thirty (30) outpatient visits for mental health and substance abuse treatment are provided through the State's Department of Services for Children, Youth, and Families (DSCYF) or

the Division of Developmental Disability Services (DDDS). DDDS provides FFS coverage for Applied Behavioral Analysis visits, beyond the initial thirty (30) outpatient visits and DSCYF provides FFS coverage for all other mental health and substance abuse treatment visits, beyond the initial thirty (30) outpatient visits. Additionally, all inpatient mental health and substance abuse treatment for children is provided FFS by DSCYF.

Also equally to the Medicaid population, children in DHCP receive all medically necessary dental benefits through a FFS delivery mechanism managed by Delaware's Division of Medicaid and Medical Assistance (DMMA).

DMMA also uses administrative funds to, through an approved Health Services Initiative, to improve the health of low-income children by increasing their access to needed vision services and glasses through a targeted, school-based initiative. DMMA administers this through a FFS structure directly with providers.

Delaware assures that it will spend no more than 10% of actual or estimated Federal expenditures for outreach and administrative costs in accordance with Section 2105(a)(2)).

3.1.2 Use of a Managed Care Delivery System for All or Some of the State's CHIP Populations

3.1.2.1 Check each of the types of entities below that the State will contract with under its managed care delivery system, and select and/or explain the method(s) of payment that the State will use:

- Managed care organization (MCO) (42 CFR 457.10)
 - Capitation payment
 - Describe population served: **The entire DHCP population.**
- Prepaid inpatient health plan (PIHP) (42 CFR 457.10)
 - Capitation payment
 - Other (please explain)
 - Describe population served:

Guidance: If the State uses prepaid ambulatory health plan(s) (PAHP) to exclusively provide non-emergency medical transportation (a NEMT PAHP), the State should not check the following box for that plan. Instead, complete section 3.1.3 for the NEMT PAHP.

- Prepaid ambulatory health plan (PAHP) (42 CFR 457.10)
 - Capitation payment
 - Other (please explain)
 - Describe population served:
- Primary care case manager (PCCM) (individual practitioners) (42 CFR 457.10)
 - Case management fee
 - Other (please explain)
- Primary care case management entity (PCCM Entity) (42 CFR 457.10)
 - Case management fee

- Shared savings, incentive payments, and/or other financial rewards for improved quality outcomes (see 42 CFR 457.1240(f))
- Other (please explain)

If PCCM entity is selected, please indicate which of the following function(s) the entity will provide (as described in 42 CFR 457.10), in addition to PCCM services:

- Provision of intensive telephonic case management
- Provision of face-to-face case management
- Operation of a nurse triage advice line
- Development of enrollee care plans
- Execution of contracts with fee-for-service (FFS) providers in the FFS program
- Oversight responsibilities for the activities of FFS providers in the FFS program
- Provision of payments to FFS providers on behalf of the State
- Provision of enrollee outreach and education activities
- Operation of a customer service call center
- Review of provider claims, utilization and/or practice patterns to conduct provider profiling and/or practice improvement
- Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers
- Coordination with behavioral health systems/providers
- Other (please describe)

- 3.1.2.2** The State assures that if its contract with an MCO, PAHP, or PIHP allows the entity to use a physician incentive plan, the contract stipulates that the entity must comply with the requirements set forth in 42 CFR 422.208 and 422.210. (42 CFR 457.1201(h), cross-referencing to 42 CFR 438.3(i))

3.1.3 Nonemergency Medical Transportation PAHPs

Guidance: Only complete Section 3.1.3 if the State uses a PAHP to exclusively provide non-emergency medical transportation (a NEMT PAHP). If a NEMT PAHP is the only managed care entity for CHIP in the State, please continue to Section 4 after checking the assurance below. If the State uses a PAHP that does not exclusively provide NEMT and/or uses other managed care entities beyond a NEMT PAHP, the State will need to complete the remaining sections within Section 3.

- The State assures that it complies with all requirements applicable to NEMT PAHPs, and through its contracts with such entities, requires NEMT PAHPs to comply with all applicable requirements, including the following (from 42 CFR 457.1206(b)):
 - All contract provisions in 42 CFR 457.1201 except those set forth in 42 CFR 457.1201(h) (related to physician incentive plans) and 42 CFR 457.1201(l) (related to mental health parity).
 - The information requirements in 42 CFR 457.1207 (see Section 3.5 below for more details).
 - The provision against provider discrimination in 42 CFR 457.1208.

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- The State responsibility provisions in 42 CFR 457.1212 (about disenrollment), 42 CFR 457.1214 (about conflict of interest safeguards), and 42 CFR 438.62(a), as cross-referenced in 42 CFR 457.1216 (about continued services to enrollees).
- The provisions on enrollee rights and protections in 42 CFR 457.1220, 457.1222, 457.1224, and 457.1226.
- The PAHP standards in 42 CFR 438.206(b)(1), as cross-referenced by 42 CFR 457.1230(a) (about availability of services), 42 CFR 457.1230(d) (about coverage and authorization of services), and 42 CFR 457.1233(a), (b) and (d) (about structure and operation standards).
- An enrollee's right to a State review under subpart K of 42 CFR 457.
- Prohibitions against affiliations with individuals debarred or excluded by Federal agencies in 42 CFR 438.610, as cross referenced by 42 CFR 457.1285.
- Requirements relating to contracts involving Indians, Indian Health Care Providers, and Indian managed care entities in 42 CFR 457.1209.

3.2. General Managed Care Contract Provisions

- 3.2.1 The State assures that it provides for free and open competition, to the maximum extent practical, in the bidding of all procurement contracts for coverage or other services, including external quality review organizations, in accordance with the procurement requirements of 45 CFR part 75, as applicable. (42 CFR 457.940(b); 42 CFR 457.1250(a), cross referencing to 42 CFR 438.356(e))
- 3.2.2 The State assures that it will include provisions in all managed care contracts that define a sound and complete procurement contract, as required by 45 CFR part 75, as applicable. (42 CFR 457.940(c))
- 3.2.3 The State assures that each MCO, PIHP, PAHP, PCCM, and PCCM entity complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its employees and contract providers observe and protect those rights (42 CFR 457.1220, cross-referencing to 42 CFR 438.100). These Federal and State laws include: Title VI of the Civil Rights Act of 1964 (45 CFR part 80), Age Discrimination Act of 1975 (45 CFR part 91), Rehabilitation Act of 1973, Title IX of the Education Amendments of 1972, Titles II and III of the Americans with Disabilities Act, and section 1557 of the Patient Protection and Affordable Care Act.
- 3.2.4 The State assures that it operates a Web site that provides the MCO, PIHP, PAHP, and PCCM entity contracts. (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(c)(3))

www.dhss.delaware.gov/DHSS/DMMA/FILES/MCO_MSA2018.PDF

3.3 Rate Development Standards and Medical Loss Ratio

- 3.3.1 The State assures that its payment rates are:
- Based on public or private payment rates for comparable services for comparable populations; and

- Consistent with actuarially sound principles as defined in 42 CFR 457.10. (42 CFR 457.1203(a))

Guidance: States that checked both boxes under 3.3.1 above do not need to make the next assurance. If the state is unable to check both boxes under 3.1.1 above, the state must check the next assurance.

- If the State is unable to meet the requirements under 42 CFR 457.1203(a), the State attests that it must establish higher rates because such rates are necessary to ensure sufficient provider participation or provider access or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services. (42 CFR 457.1203(b))

3.3.2 The State assures that its rates are designed to reasonably achieve a medical loss ratio standard equal to at least 85 percent for the rate year and provide for reasonable administrative costs. (42 CFR 457.1203(c))

3.3.3 The State assures that it will provide to CMS, if requested by CMS, a description of the manner in which rates were developed in accordance with the requirements of 42 CFR 457.1203(a) through (c). (42 CFR 457.1203(d))

3.3.4 The State assures that it annually submits to CMS a summary description of the reports pertaining to the medical loss ratio received from the MCOs, PIHPs, and PAHPs. (42 CFR 457.1203(e), cross referencing to 42 CFR 438.74(a))

3.3.5 Does the State require an MCO, PIHP, or PAHP to pay remittances through the contract for not meeting the minimum MLR required by the State? (42 CFR 457.1203(e), cross referencing to 42 CFR 438.74(b)(1))

- No, the State does not require any MCO, PIHP, or PAHP to pay remittances.
- Yes, the State requires all MCOs, PIHPs, and PAHPs to pay remittances.
- Yes, the State requires some, but not all, MCOs, PIHPs, and PAHPs to pay remittances.

If the State requests some, but not all, MCOs, PIHPs, and PAHPs to pay remittances through the contract for not meeting the minimum MLR required by the State, please describe which types of managed care entities are and are not required to pay remittances. For example, if a state requires a medical MCO to pay a remittances but not a dental PAHP, please include this information.

If the answer to the assurance above is yes for any or all managed care entities, please answer the next assurance:

- The State assures that if a remittance is owed by an MCO, PIHP, or PAHP to the State, the State:
- Reimburses CMS for an amount equal to the Federal share of the remittance, taking into account applicable differences in the Federal matching rate; and
 - Submits a separate report describing the methodology used to determine the State and Federal share of the remittance with the annual report provided to CMS that summarizes the reports received from the MCOs, PIHPs, and PAHPs. (42 CFR 457.1203(e), cross referencing to

42 CFR 438.74(b))

- 3.3.6 The State assures that each MCO, PIHP, and PAHP calculates and reports the medical loss ratio in accordance with 42 CFR 438.8. (42 CFR 457.1203(f))

3.4 Enrollment

- The State assures that its contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities provide that the MCO, PIHP, PAHP, PCCM or PCCM entity:
- Accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by CMS), up to the limits set under the contract (42 CFR 457.1201(d), cross-referencing to 42 CFR 438.3(d)(1));
 - Will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll (42 CFR 457.1201(d), cross-referencing to 42 CFR 438.3(d)(3)); and
 - Will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, national origin, sex, sexual orientation, gender identity or disability. (42 CFR 457.1201(d), cross-referencing to 438.3(d)(4))

3.4.1 Enrollment Process

- 3.4.1.1 The State assures that it provides informational notices to potential enrollees in an MCO, PIHP, PAHP, PCCM, or PCCM entity that includes the available managed care entities, explains how to select an entity, explains the implications of making or not making an active choice of an entity, explains the length of the enrollment period as well as the disenrollment policies, and complies with the information requirements in 42 CFR 457.1207 and accessibility standards established under 42 CFR 457.340. (42 CFR 457.1210(c))

- 3.4.1.2 The State assures that its enrollment system gives beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM, or PCCM entity priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM, or PCCM entity does not have the capacity to accept all those seeking enrollment under the program. (42 CFR 457.1210(b))

- 3.4.1.3 Does the State use a default enrollment process to assign beneficiaries to an MCO, PIHP, PAHP, PCCM, or PCCM entity? (42 CFR 457.1210(a))

- Yes
 No

If the State uses a default enrollment process, please make the following assurances:

- The State assigns beneficiaries only to qualified MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities that are not subject to the intermediate sanction of having suspension of all new enrollment (including default enrollment) under 42 CFR 438.702 and have capacity to enroll beneficiaries. (42 CFR 457.1210(a)(1)(i))

- The State maximizes continuation of existing provider-beneficiary relationships under 42 CFR 457.1210(a)(1)(ii) or if that is not possible, distributes the beneficiaries equitably and does not arbitrarily exclude any MCO, PIHP, PAHP, PCCM or PCCM entity from being considered. (42 CFR 457.1210(a)(1)(ii), 42 CFR 457.1210(a)(1)(iii))

3.4.2 Disenrollment

- 3.4.2.1 The State assures that the State will notify enrollees of their right to disenroll consistent with the requirements of 42 CFR 438.56 at least annually. (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(f)(2))
- 3.4.2.2 The State assures that the effective date of an approved disenrollment, regardless of the procedure followed to request the disenrollment, will be no later than the first day of the second month following the month in which the enrollee requests disenrollment or the MCO, PIHP, PAHP, PCCM or PCCM entity refers the request to the State. (42 CFR 457.1212, cross-referencing to 438.56(e)(1))
- 3.4.2.3 If a beneficiary disenrolls from an MCO, PIHP, PAHP, PCCM, or PCCM entity, the State assures that the beneficiary is provided the option to enroll in another plan or receive benefits from an alternative delivery system. (Section 2103(f)(3) of the Social Security Act, incorporating section 1932(a)(4); 42 CFR 457.1212, cross referencing to 42 CFR 438.56; State Health Official Letter #09-008)
- 3.4.2.4 **MCO, PIHP, PAHP, PCCM and PCCM Entity Requests for Disenrollment.**
 - The State assures that contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities describe the reasons for which an MCO, PIHP, PAHP, PCCM and PCCM entity may request disenrollment of an enrollee, if any. (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(b))

Guidance: Reasons for disenrollment by the MCO, PIHP, PAHP, PCCM, and PCCM entity must be specified in the contract with the State. Reasons for disenrollment may not include an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, PCCM or PCCM entity seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees). (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(b)(2))

3.4.2.5 Enrollee Requests for Disenrollment.

Guidance: The State may also choose to limit disenrollment from the MCO, PIHP, PAHP, PCCM, or PCCM entity, except for either: 1) for cause, at any time; or 2) without cause during the latter of the 90 days after the beneficiary's initial enrollment or the State sends the beneficiary notice of that enrollment, at least once every 12 months, upon reenrollment if the temporary loss of CHIP eligibility caused the beneficiary to miss the annual disenrollment opportunity, or when the State imposes the intermediate sanction specified in 42 CFR 438.702(a)(4). (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(c))

Does the State limit disenrollment from an MCO, PIHP, PAHP, PCCM and PCCM entity by an enrollee? (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(c))

- Yes
 No

If the State limits disenrollment by the enrollee from an MCO, PIHP, PAHP, PCCM and PCCM entity, please make the following assurances (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(c)):

- The State assures that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period. (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(f)(1))
- The State assures that beneficiary requests to disenroll for cause will be permitted at any time by the MCO, PIHP, PAHP, PCCM or PCCM entity. (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(c)(1) and (d)(2))
- The State assures that beneficiary requests for disenrollment without cause will be permitted by the MCO, PIHP, PAHP, PCCM or PCCM entity at the following times:
- During the 90 days following the date of the beneficiary's initial enrollment into the MCO, PIHP, PAHP, PCCM, or PCCM entity, or during the 90 days following the date the State sends the beneficiary notice of that enrollment, whichever is later;
 - At least once every 12 months thereafter;
 - If the State plan provides for automatic reenrollment for an individual who loses CHIP eligibility for a period of 2 months or less and the temporary loss of CHIP eligibility has caused the beneficiary to miss the annual disenrollment opportunity; and
 - When the State imposes the intermediate sanction on the MCO, PIHP, PAHP, PCCM or PCCM entity specified in 42 CFR 438.702(a)(4). (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(c)(2))

- 3.4.2.6** The State assures that the State ensures timely access to a State review for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment. (42 CFR 457.1212, cross-referencing to 42 CFR 438.56(f)(2))

3.5 Information Requirements for Enrollees and Potential Enrollees

- 3.5.1** The State assures that it provides, or ensures its contracted MCOs, PAHPs, PIHPs, PCCMs and PCCM entities provide, all enrollment notices, informational materials, and instructional materials related to enrollees and potential enrollees in accordance with the terms of 42 CFR 457.1207, cross-referencing to 42 CFR 438.10.
- 3.5.2** The State assures that all required information provided to enrollees and potential enrollees are in a manner and format that may be easily understood and is readily accessible by such enrollees and potential enrollees. (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(c)(1))
- 3.5.3** The State assures that it operates a Web site that provides the content specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(g)-(i) either di-

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rectly or by linking to individual MCO, PIHP, PAHP and PCCM entity Web sites.

3.5.4

The State assures that it has developed and requires each MCO, PIHP, PAHP and PCCM entity to use:

- Definitions for the terms specified under 42 CFR 438.10(c)(4)(i), and
- Model enrollee handbooks, and model enrollee notices. (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(c)(4))

3.5.5

If the State, MCOs, PIHPs, PAHPs, PCCMs or PCCM entities provide the information required under 42 CFR 457.1207 electronically, check this box to confirm that the State assures that it meets the requirements under 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(c)(6) for providing the material in an accessible manner. Including that:

- The format is readily accessible;
- The information is placed in a location on the State, MCO's, PIHP's, PAHP's, or PCCM's, or PCCM entity's Web site that is prominent and readily accessible;
- The information is provided in an electronic form which can be electronically retained and printed;
- The information is consistent with the content and language requirements in 42 CFR 438.10; and
- The enrollee is informed that the information is available in paper form without charge upon request and is provided the information upon request within 5 business days.

3.5.6

The State assures that it meets the language and format requirements set forth in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(d), including but not limited to:

- Establishing a methodology that identifies the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State, and in each MCO, PIHP, PAHP, or PCCM entity service area;
- Making oral interpretation available in all languages and written translation available in each prevalent non-English language;
- Requiring each MCO, PIHP, PAHP, and PCCM entity to make its written materials that are critical to obtaining services available in the prevalent non-English languages in its particular service area;
- Making interpretation services available to each potential enrollee and requiring each MCO, PIHP, PAHP, and PCCM entity to make those services available free of charge to each enrollee; and
- Notifying potential enrollees, and requiring each MCO, PIHP, PAHP, and PCCM entity to notify its enrollees:
 - That oral interpretation is available for any language and written translation is available in prevalent languages;
 - That auxiliary aids and services are available upon request and at no cost for enrollees with disabilities; and
 - How to access the services in 42 CFR 457.1207, cross-referencing 42 CFR 438.10(d)(5)(i) and (ii).

3.5.7

The State assures that the State or its contracted representative provides the information specified in 42 CFR 457.1207, cross-referencing to 438.10(e)(2), and includes the information either in paper or electronic format, to all potential enrollees at the time the potential enrollee becomes eligible to enroll in a voluntary managed care program or is first required to enroll in a mandatory

managed care program and within a timeframe that enables the potential enrollee to use the information to choose among the available MCOs, PIHPs, PAHPs, PCCMs and PCCM entities:

- Information about the potential enrollee's right to disenroll consistent with the requirements of 42 CFR 438.56 and which explains clearly the process for exercising this disenrollment right, as well as the alternatives available to the potential enrollee based on their specific circumstance;
- The basic features of managed care;
- Which populations are excluded from enrollment in managed care, subject to mandatory enrollment, or free to enroll voluntarily in the program;
- The service area covered by each MCO, PIHP, PAHP, PCCM, or PCCM entity;
- Covered benefits including:
 - Which benefits are provided by the MCO, PIHP, or PAHP; and which, if any, benefits are provided directly by the State; and
 - For a counseling or referral service that the MCO, PIHP, or PAHP does not cover because of moral or religious objections, where and how to obtain the service;
- The provider directory and formulary information required in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(h) and (i);
- Any cost-sharing for the enrollee that will be imposed by the MCO, PIHP, PAHP, PCCM, or PCCM entity consistent with those set forth in the State plan;
- The requirements for each MCO, PIHP or PAHP to provide adequate access to covered services, including the network adequacy standards established in 42 CFR 457.1218, cross-referencing 42 CFR 438.68;
- The MCO, PIHP, PAHP, PCCM and PCCM entity's responsibilities for coordination of enrollee care; and
- To the extent available, quality and performance indicators for each MCO, PIHP, PAHP and PCCM entity, including enrollee satisfaction.

- 3.5.8** ☒ The State assures that it will provide the information specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(f) to all enrollees of MCOs, PIHPs, PAHPs and PCCM entities, including that the State must notify all enrollees of their right to disenroll consistent with the requirements of 42 CFR 438.56 at least annually.
- 3.5.9** ☒ The State assures that each MCO, PIHP, PAHP and PCCM entity will provide the information specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(f) to all enrollees of MCOs, PIHPs, PAHPs and PCCM entities, including that:
- The MCO, PIHP, PAHP and, when appropriate, the PCCM entity, must make a good faith effort to give written notice of termination of a contracted provider within the timeframe specified in 42 CFR 438.10(f), and
 - The MCO, PIHP, PAHP and, when appropriate, the PCCM entity must make available, upon request, any physician incentive plans in place as set forth in 42 CFR 438.3(i).
- 3.5.10** ☒ The State assures that each MCO, PIHP, PAHP and PCCM entity will provide enrollees of that MCO, PIHP, PAHP or PCCM entity an enrollee handbook that meets the requirements as applicable to the MCO, PIHP, PAHP and PCCM entity, specified in 42 CFR 457.1207, cross-referencing to 42 CFR

438.10(g)(1)-(2), within a reasonable time after receiving notice of the beneficiary's enrollment, by a method consistent with 42 CFR 438.10(g)(3), and including the following items:

- Information that enables the enrollee to understand how to effectively use the managed care program, which, at a minimum, must include:
 - Benefits provided by the MCO, PIHP, PAHP or PCCM entity;
 - How and where to access any benefits provided by the State, including any cost sharing, and how transportation is provided; and
 - In the case of a counseling or referral service that the MCO, PIHP, PAHP, or PCCM entity does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM entity must inform enrollees that the service is not covered by the MCO, PIHP, PAHP, or PCCM entity and how they can obtain information from the State about how to access these services;
- The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled;
- Procedures for obtaining benefits, including any requirements for service authorizations and/or referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider;
- The extent to which, and how, after-hours and emergency coverage are provided, including:
 - What constitutes an emergency medical condition and emergency services;
 - The fact that prior authorization is not required for emergency services; and
 - The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care;
- Any restrictions on the enrollee's freedom of choice among network providers;
- The extent to which, and how, enrollees may obtain benefits, including family planning services and supplies from out-of-network providers;
- Cost sharing, if any is imposed under the State plan;
- Enrollee rights and responsibilities, including the elements specified in 42 CFR §438.100;
- The process of selecting and changing the enrollee's primary care provider;
- Grievance, appeal, and review procedures and timeframes, consistent with 42 CFR 457.1260, in a State-developed or State-approved description, including:
 - The right to file grievances and appeals;
 - The requirements and timeframes for filing a grievance or appeal;
 - The availability of assistance in the filing process; and
 - The right to request a State review after the MCO, PIHP or PAHP has made a determination on an enrollee's appeal which is adverse to the enrollee;

- How to access auxiliary aids and services, including additional information in alternative formats or languages;
- The toll-free telephone number for member services, medical management, and any other unit providing services directly to enrollees; and
- Information on how to report suspected fraud or abuse.

- 3.5.11** ☒ The State assures that each MCO, PIHP, PAHP and PCCM entity will give each enrollee notice of any change that the State defines as significant in the information specified in the enrollee handbook at least 30 days before the intended effective date of the change. (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(g)(4))
- 3.5.12** ☒ The State assures that each MCO, PIHP, PAHP and when appropriate, PCCM entity, will make available a provider directory for the MCO's, PIHP's, PAHP's or PCCM entity's network providers, including for physicians (including specialists), hospitals, pharmacies, and behavioral health providers, that includes information as specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(h)(1)-(2) and (4).
- 3.5.13** ☒ The State assures that each MCO, PIHP, PAHP and when appropriate, PCCM entity, will update any information included in a paper provider directory at least monthly and in an electronic provider directories as specified in 42 CFR 438.10(h)(3). (42 CFR 457.1207, cross-referencing to 42 CFR 438.10(h)(3))
- 3.5.14** ☒ The State assures that each MCO, PIHP, PAHP and when appropriate, PCCM entity, will make available the MCO's, PIHP's, PAHP's, or PCCM entity's formulary that meets the requirements specified in 42 CFR 457.1207, cross-referencing to 42 CFR 438.10(i), including:
- Which medications are covered (both generic and name brand); and
 - What tier each medication is on.
- 3.5.15** ☒ The State assures that each MCO, PIHP, PAHP, PCCM and PCCM entity follows the requirements for marketing activities under 42 CFR 457.1224, cross-referencing to 42 CFR 438.104 (except 42 CFR 438.104(c)).

Guidance: Requirements for marketing activities include, but are not limited to, that the MCO, PIHP, PAHP, PCCM, or PCCM entity does not distribute any marketing materials without first obtaining State approval; distributes the materials to its entire service areas as indicated in the contract; does not seek to influence enrollment in conjunction with the sale or offering of any private insurance; and does not, directly or indirectly, engage in door-to-door, telephone, email, texting, or other cold-call marketing activities. (42 CFR 104(b))

Guidance: Only States with MCOs, PIHPs, or PAHPs need to answer the remaining assurances in Section 3.5 (3.5.16 through 3.5.18).

- 3.5.16** ☒ The State assures that each MCO, PIHP and PAHP protects communications between providers and enrollees under 42 CFR 457.1222, cross-referencing to 42 CFR 438.102.
- 3.5.17** ☒ The State assures that MCOs, PIHPs, and PAHPs have arrangements and procedures that prohibit the MCO, PIHP, and PAHP from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of

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the MCO, PAHP, or PIHP for the purpose of influencing the individual to enroll with the entity. (42 CFR 457.1280(b)(2))

Guidance: States should also complete Section 3.9, which includes additional provisions about the notice procedures for grievances and appeals.

3.5.18 The State assures that each contracted MCO, PIHP, and PAHP comply with the notice requirements specified for grievances and appeals in accordance with the terms of 42 CFR 438, Subpart F, except that the terms of 42 CFR 438.420 do not apply and that references to reviews should be read to refer to reviews as described in 42 CFR 457, Subpart K. (42 CFR 457.1260)

3.6 Benefits and Services

Guidance: The State should also complete Section 3.10 (Program Integrity).

3.6.1 The State assures that MCO, PIHP, PAHP, PCCM entity, and PCCM contracts involving Indians, Indian health care providers, and Indian managed care entities comply with the requirements of 42 CFR 438.14. (42 CFR 457.1209)

[Delaware does not have any state or federally recognized Indian tribes.](#)

3.6.2 The State assures that all services covered under the State plan are available and accessible to enrollees. (42 CFR 457.1230(a), cross-referencing to 42 CFR 438.206)

3.6.3 The State assures that it:

- Publishes the State's network adequacy standards developed in accordance with 42 CFR 457.1218, cross-referencing 42 CFR 438.68(b)(1) on the Web site required by 42 CFR 438.10;
- Makes available, upon request, the State's network adequacy standards at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services. (42 CFR 457.1218, cross-referencing 42 CFR 438.68(e))

Guidance: Only States with MCOs, PIHPs, or PAHPs need to complete the remaining assurances in Section 3.6 (3.6.4 through 3.6.20).

3.6.4 The State assures that each MCO, PAHP and PIHP meet the State's network adequacy standards. (42 CFR 457.1218, cross-referencing 42 CFR 438.68; 42 CFR 457.1230(a), cross-referencing to 42 CFR 438.206)

3.6.5 The State assures that each MCO, PIHP, and PAHP includes within its network of credentialed providers:

- A sufficient number of providers to provide adequate access to all services covered under the contract for all enrollees, including those with limited English proficiency or physical or mental disabilities;
- Women's health specialists to provide direct access to covered care necessary to provide women's routine and preventative health care services for female enrollees; and
- Family planning providers to ensure timely access to covered services. (42 CFR 457.1230(a), cross-referencing to 42 CFR 438.206(b))

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- 3.6.6** The State assures that each contract under 42 CFR 457.1201 permits an enrollee to choose his or her network provider. (42 CFR 457.1201(j), cross-referencing 42 CFR 438.3(l))
- 3.6.7** The State assures that each MCO, PIHP, and PAHP provides for a second opinion from a network provider, or arranges for the enrollee to obtain one outside the network, at no cost. (42 CFR 457.1230(a), cross-referencing to 42 CFR 438.206(b)(3))
- 3.6.8** The State assures that each MCO, PIHP, and PAHP ensures that providers, in furnishing services to enrollees, provide timely access to care and services, including by:
- Requiring the contract to adequately and timely cover out-of-network services if the provider network is unable to provide necessary services covered under the contract to a particular enrollee and at a cost to the enrollee that is no greater than if the services were furnished within the network;
 - Requiring the MCO, PIHP and PAHP meet and its network providers to meet State standards for timely access to care and services, taking into account the urgency of the need for services;
 - Ensuring that the hours of operation for a network provider are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid or CHIP Fee-For-Service, if the provider serves only Medicaid or CHIP enrollees;
 - Ensuring that the MCO, PIHP and PAHP makes available services include in the contract on a 24 hours a day, 7 days a week basis when medically necessary;
 - Establishing mechanisms to ensure compliance by network providers;
 - Monitoring network providers regularly to determine compliance;
 - Taking corrective action if there is a failure to comply by a network provider. (42 CFR 457.1230(a), cross-referencing to 42 CFR 438.206(b)(4) and (5) and (c))
- 3.6.9** The State assures that each MCO, PIHP, and PAHP has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care. (42 CFR 457.1230(b), cross-referencing to 42 CFR 438.207)
- 3.6.10** The State assures that each MCO, PIHP, and PAHP will be required to submit documentation to the State, at the time of entering into a contract with the State, on an annual basis, and at any time there has been a significant change to the MCO, PIHP, or PAHP's operations that would affect the adequacy of capacity and services, to demonstrate that each MCO, PIHP, and PAHP for the anticipated number of enrollees for the service area:
- Offers an appropriate range of preventative, primary care and specialty services; and
 - Maintains a provider network that is sufficient in number, mix, and geographic distribution. (42 CFR 457.1230, cross-referencing to 42 CFR 438.207(b))

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3.6.11 ☒

Except that 42 CFR 438.210(a)(5) does not apply to CHIP, the State assures that its contracts with each MCO, PIHP, or PAHP comply with the coverage of services requirements under 42 CFR 438.210, including:

- Identifying, defining, and specifying the amount, duration, and scope of each service that the MCO, PIHP, or PAHP is required to offer; and
- Permitting an MCO, PIHP, or PAHP to place appropriate limits on a service. (42 CFR 457.1230(d), cross referencing to 42 CFR 438.210(a) except that 438.210(a)(5) does not apply to CHIP contracts)

3.6.12 ☒

Except that 438.210(b)(2)(iii) does not apply to CHIP, the State assures that its contracts with each MCO, PIHP, or PAHP comply with the authorization of services requirements under 42 CFR 438.210, including that:

- The MCO, PIHP, or PAHP and its subcontractors have in place and follow written policies and procedures;
- The MCO, PIHP, or PAHP have in place mechanisms to ensure consistent application of review criteria and consult with the requesting provider when appropriate; and
- Any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested be made by an individual with appropriate expertise in addressing the enrollee's medical, or behavioral health needs. (42 CFR 457.1230(d), cross referencing to 42 CFR 438.210(b), except that 438.210(b)(2)(iii) does not apply to CHIP contracts)

3.6.13 ☒

The State assures that its contracts with each MCO, PIHP, or PAHP require each MCO, PIHP, or PAHP to notify the requesting provider and given written notice to the enrollee of any adverse benefit determination to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. (42 CFR 457.1230(d), cross-referencing to 42 CFR 438.210(c))

3.6.14 ☒

The State assures that its contracts with each MCO, PIHP, or PAHP provide that compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee. (42 CFR 457.1230(d), cross-referencing to 42 CFR 438.210(e))

3.6.15 ☒

The State assures that it has a transition of care policy that meets the requirements of 438.62(b)(1) and requires that each contracted MCO, PIHP, and PAHP implements the policy. (42 CFR 457.1216, cross-referencing to 42 CFR 438.62)

3.6.16 ☒

The State assures that each MCO, PIHP, and PAHP has implemented procedures to deliver care to and coordinate services for all enrollees in accordance with 42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208, including:

- Ensure that each enrollee has an ongoing source of care appropriate to his or her needs;
- Ensure that each enrollee has a person or entity formally designated as primarily responsible for coordinating the services accessed by the enrollee;
- Provide the enrollee with information on how to contact their design-

nated person or entity responsible for the enrollee's coordination of services;

- Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee between settings of care; with services from any other MCO, PIHP, or PAHP; with fee-for-service services; and with the services the enrollee receives from community and social support providers;
- Make a best effort to conduct an initial screening of each enrollee's needs within 90 days of the effective date of enrollment for all new enrollees;
- Share with the State or other MCOs, PIHPs, or PAHPs serving the enrollee the results of any identification and assessment of the enrollee's needs;
- Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards; and
- Ensure that each enrollee's privacy is protected in the process of coordinating care is protected with the requirements of 45 CFR parts 160 and 164 subparts A and E. (42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(b))

Guidance: For assurances 3.6.17 through 3.6.20, applicability to PIHPs and PAHPs is based a determination by the State in relation to the scope of the entity's services and on the way the State has organized its delivery of managed care services, whether a particular PIHP or PAHP is required to implement the mechanisms for identifying, assessing, and producing a treatment plan for an individual with special health care needs. (42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(a)(2))

- 3.6.17** The State assures that it has implemented mechanisms for identifying to MCOs, PIHPs, and PAHPs enrollees with special health care needs who are eligible for assessment and treatment services under 42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(c) and included the mechanism in the State's quality strategy.
- 3.6.18** The State assures that each applicable MCO, PIHP, and PAHP implements the mechanisms to comprehensively assess each enrollee identified by the state as having special health care needs. (42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(c)(2))
- 3.6.19** The State assures that each MCO, PIHP, and PAHP will produce a treatment or service plan that meets the following requirements for enrollees identified with special health care needs:
- Is in accordance with applicable State quality assurance and utilization review standards;
 - Reviewed and revised upon reassessment of functional need, at least every 12 months, or when the enrollee's circumstances or needs change significantly. (42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(c)(3))
- 3.6.20** The State assures that each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist as appropriate for the enrollee's condition and identified needs for enrollees identified with special

health care needs who need a course of treatment or regular care monitoring. (42 CFR 457.1230(c), cross-referencing to 42 CFR 438.208(c)(4))

3.7 Operations

- 3.7.1 The State assures that it has established a uniform credentialing and recredentialing policy that addresses acute, primary, behavioral, and substance use disorders providers and requires each MCO, PIHP and PAHP to follow those policies. (42 CFR 457.1233(a), cross-referencing 42 CFR 438.214(b)(1))

Guidance: Only States with MCOs, PIHPs, or PAHPs need to answer the remaining assurances in Section 3.7 (3.7.2 through 3.7.9).

- 3.7.2 The State assures each contracted MCO, PIHP and PAHP will comply with the provider selection requirements in 42 CFR 457.1208 and 457.1233(a), cross-referencing 42 CFR 438.12 and 438.214, including that:
- Each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of network providers (42 CFR 457.1233(a), cross-referencing 42 CFR 438.214(a));
 - MCO, PIHP, and PAHP network provider selection policies and procedures do not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment (42 CFR 457.1233(a), cross-referencing 42 CFR 438.214(c));
 - MCOs, PIHPs, and PAHPs do not discriminate in the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification, solely on the basis of that license or certification (42 CFR 457.1208, cross referencing 42 CFR 438.12(a));
 - If an MCO, PIHP, or PAHP declines to include individual or groups of providers in the MCO, PIHP, or PAHP's provider network, the MCO, PIHP, and PAHP gives the affected providers written notice of the reason for the decision (42 CFR 457.1208, cross referencing 42 CFR 438.12(a)); and
 - MCOs, PIHPs, and PAHPs do not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act. (42 CFR 457.1233(a), cross-referencing 42 CFR 438.214(d)).
- 3.7.3 The State assures that each contracted MCO, PIHP, and PAHP complies with the subcontractual relationships and delegation requirements in 42 CFR 457.1233(b), cross-referencing 42 CFR 438.230, including that:
- The MCO, PIHP, or PAHP maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with the State;
 - All contracts or written arrangements between the MCO, PIHP, or PAHP and any subcontractor specify that all delegated activities or obligations, and related reporting responsibilities, are specified in the contract or written agreement, the subcontractor agrees to perform the delegated activities and reporting responsibilities specified in compliance with the MCO's, PIHP's, or PAHP's contract obligations, and the contract or written arrangement must either provide for revocation of the delegation of activi-

ties or obligations, or specify other remedies in instances where the State or the MCO, PIHP, or PAHP determine that the subcontractor has not performed satisfactorily;

- All contracts or written arrangements between the MCO, PIHP, or PAHP and any subcontractor must specify that the subcontractor agrees to comply with all applicable CHIP laws, regulations, including applicable subregulatory guidance and contract provisions; and
- The subcontractor agrees to the audit provisions in 438.230(c)(3).

3.7.4 The State assures that each contracted MCO and, when applicable, each PIHP and PAHP, adopts and disseminates practice guidelines that are based on valid and reliable clinical evidence or a consensus of providers in the particular field; consider the needs of the MCO's, PIHP's, or PAHP's enrollees; are adopted in consultation with network providers; and are reviewed and updated periodically as appropriate. (42 CFR 457.1233(c), cross referencing 42 CFR 438.236(b) and (c))

3.7.5 The State assures that each contracted MCO and, when applicable, each PIHP and PAHP makes decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the practice guidelines. (42 CFR 457.1233(c), cross referencing 42 CFR 438.236(d))

3.7.6 The State assures that each contracted MCO, PIHP, and PAHP maintains a health information system that collects, analyzes, integrates, and reports data consistent with 42 CFR 438.242. The systems must provide information on areas including, but not limited to, utilization, claims, grievances and appeals, and disenrollments for other than loss of CHIP eligibility. (42 CFR 457.1233(d), cross referencing 42 CFR 438.242)

3.7.7 The State assures that it reviews and validates the encounter data collected, maintained, and submitted to the State by the MCO, PIHP, or PAHP to ensure it is a complete and accurate representation of the services provided to the enrollees under the contract between the State and the MCO, PIHP, or PAHP and meets the requirements 42 CFR 438.242 of this section. (42 CFR 457.1233(d), cross referencing 42 CFR 438.242)

3.7.8 The State assures that it will submit to CMS all encounter data collected, maintained, submitted to the State by the MCO, PIHP, and PAHP once the State has reviewed and validated the data based on the requirements of 42 CFR 438.242. (CMS State Medicaid Director Letter #13-004)

3.7.9 The State assures that each contracted MCO, PIHP and PAHP complies with the privacy protections under 42 CFR 457.1110. (42 CFR 457.1233(e))

3.8 Beneficiary Protections

3.8.1 The State assures that each MCO, PIHP, PAHP, PCCM and PCCM entity has written policies regarding the enrollee rights specified in 42 CFR 438.100. (42 CFR 457.1220, cross-referencing to 42 CFR 438.100(a)(1))

3.8.2 The State assures that its contracts with an MCO, PIHP, PAHP, PCCM, or PCCM entity include a guarantee that the MCO, PIHP, PAHP, PCCM, or PCCM entity will not avoid costs for services covered in its contract by refer-

ring enrollees to publicly supported health care resources. (42 CFR 457.1201(p))

- 3.8.3** The State assures that MCOs, PIHPs, and PAHPs do not hold the enrollee liable for the following:
- The MCO's, PIHP's or PAHP's debts, in the event of the entity's solvency. (42 CFR 457.1226, cross-referencing to 42 CFR 438.106(a))
 - Covered services provided to the enrollee for which the State does not pay the MCO, PIHP or PAHP or for which the State, MCO, PIHP, or PAHP does not pay the individual or the health care provider that furnished the services under a contractual, referral or other arrangement. (42 CFR 457.1226, cross-referencing to 42 CFR 438.106(b))
 - Payments for covered services furnished under a contract, referral or other arrangement that are in excess of the amount the enrollee would owe if the MCO, PIHP or PAHP covered the services directly. (42 CFR 457.1226, cross-referencing to 42 CFR 438.106(c))

3.9 Grievances and Appeals

Guidance: Only States with MCOs, PIHPs, or PAHPs need to complete Section 3.9. States with PCCMs and/or PCCM entities should be adhering to the State's review process for benefits.

- 3.9.1** The State assures that each MCO, PIHP, and PAHP has a grievance and appeal system in place that allows enrollees to file a grievance and request an appeal. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(a) and 438.402(c))
- 3.9.2** The State assures that each MCO, PIHP, and PAHP has only one level of appeal for enrollees. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(b))
- 3.9.3** The State assures that an enrollee may request a State review after receiving notice that the adverse benefit determination is upheld, or after an MCO, PIHP, or PAHP fails to adhere to the notice and timing requirements in 42 CFR 438.408. (42 CFR 457.1260, cross-referencing to 438.402(c))
- 3.9.4.** Does the state offer and arrange for an external medical review?
- Yes
- No

Guidance: Only states that answered yes to assurance 3.9.4 need to complete the next assurance (3.9.5).

- 3.9.5** The State assures that the external medical review is:
- At the enrollee's option and not required before or used as a deterrent to proceeding to the State review;
 - Independent of both the State and MCO, PIHP, or PAHP;
 - Offered without any cost to the enrollee; and
 - Not extending any of the timeframes specified in 42 CFR 438.408. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(a) and 438.402(c)(1)(i))
- 3.9.6** The State assures that an enrollee may file a grievance with the MCO, PIHP, or PAHP at any time. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(a) and 438.402(c)(2)(i))

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- 3.9.7** The State assures that an enrollee has 60 calendar days from the date on an adverse benefit determination notice to file a request for an appeal to the MCO, PIHP, or PAHP. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(a) and 438.402(c)(2)(ii))
- 3.9.8** The State assures that an enrollee may file a grievance and request an appeal either orally or in writing. (42 CFR 457.1260, cross-referencing to 42 CFR 438.402(a) and 438.402(c)(3)(i))
- 3.9.9** The State assures that each MCO, PIHP, and PAHP gives enrollees timely and adequate notice of an adverse benefit determination in writing consistent with the requirements below in Section 3.9.10 and in 42 CFR 438.10.
- 3.9.10** The State assures that the notice of an adverse benefit determination explains:
- The adverse benefit determination.
 - The reasons for the adverse benefit determination, including the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's adverse benefit determination. Such information includes medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.
 - The enrollee's right to request an appeal of the MCO's, PIHP's, or PAHP's adverse benefit determination, including information on exhausting the MCO's, PIHP's, or PAHP's one level of appeal and the right to request a State review.
 - The procedures for exercising the rights specified above under this assurance.
 - The circumstances under which an appeal process can be expedited and how to request it. (42 CFR 457.1260, cross-referencing to 42 CFR 438.404(b))
- 3.9.11** The State assures that the notice of an adverse benefit determination is provided in a timely manner in accordance with 42 CFR 457.1260. (42 CFR 457.1260, cross-referencing to 42 CFR 438.404(c))
- 3.9.12** The State assures that MCOs, PIHPs, and PAHPs give enrollees reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal. This includes, but is not limited to, auxiliary aids and services upon request, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability. (42 CFR 457.1260, cross-referencing to 42 CFR 438.406(a))
- 3.9.13** The state makes the following assurances related to MCO, PIHP, and PAHP processes for handling enrollee grievances and appeals:
- Individuals who make decisions on grievances and appeals were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.
 - Individuals who make decisions on grievances and appeals, if deciding any of the following, are individuals who have the appropriate clinical expertise in treating the enrollee's condition or disease:
 - An appeal of a denial that is based on lack of medical necessity.

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- A grievance regarding denial of expedited resolution of an appeal.
 - A grievance or appeal that involves clinical issues.
 - All comments, documents, records, and other information submitted by the enrollee or their representative will be taken into account, without regard to whether such information was submitted or considered in the initial adverse benefit determination.
 - Enrollees have a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments.
 - Enrollees are provided the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the MCO, PIHP or PAHP (or at the direction of the MCO, PIHP or PAHP) in connection with the appeal of the adverse benefit determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for appeals.
 - The enrollee and his or her representative or the legal representative of a deceased enrollee's estate are included as parties to the appeal. (42 CFR 457.1260, cross-referencing to 42 CFR 438.406(b))
- 3.9.14** The State assures that standard grievances are resolved (including notice to the affected parties) within 90 calendar days from the day the MCO, PIHP, or PAHP receives the grievance. (42 CFR 457.1260, cross-referencing to 42 CFR 438.408(b))
- 3.9.15** The State assures that standard appeals are resolved (including notice to the affected parties) within 30 calendar days from the day the MCO, PIHP, or PAHP receives the appeal. The MCO, PIHP, or PAHP may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or the MCO, PIHP, or PAHP shows that there is need for additional information and that the delay is in the enrollee's interest. (42 CFR 457.1260, cross-referencing to 42 CFR 42 CFR 438.408(b) and (c))
- 3.9.16** The State assures that each MCO, PIHP, and PAHP establishes and maintains an expedited review process for appeals that is no longer than 72 hours after the MCO, PIHP, or PAHP receives the appeal. The expedited review process applies when the MCO, PIHP, or PAHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function. (42 CFR 457.1260, cross-referencing to 42 CFR 438.408(b) and (c), and 42 CFR 438.410(a))
- 3.9.17** The State assures that if an MCO, PIHP, or PAHP denies a request for expedited resolution of an appeal, it transfers the appeal within the timeframe for standard resolution in accordance with 42 CFR 438.408(b)(2). (42 CFR 457.1260, cross-referencing to 42 CFR 438.410(c)(1))
- 3.9.18** The State assures that if the MCO, PIHP, or PAHP extends the timeframes for an appeal not at the request of the enrollee or it denies a request for an expedited resolution of an appeal, it completes all of the following:
- Make reasonable efforts to give the enrollee prompt oral notice of the de-

lay.

- Within 2 calendar days give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision.
- Resolve the appeal as expeditiously as the enrollee's health condition requires and no later than the date the extension expires. (42 CFR 457.1260, cross-referencing to 42 CFR 438.408(c) and 42 CFR 438.410(c))

3.9.19 The State assures that if an MCO, PIHP, or PAHP fails to adhere to the notice and timing requirements in this section, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process and the enrollee may initiate a State review. (42 CFR 457.1260, cross-referencing to 42 CFR 438.408(c)(3))

3.9.20 The State assures that has established a method that an MCO, PIHP, and PAHP will use to notify an enrollee of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at 42 CFR 438.10. (42 CFR 457.1260, cross referencing to 42 CFR 457.408(d)(1))

3.9.21 For all appeals, the State assures that each contracted MCO, PIHP, and PAHP provides written notice of resolution in a format and language that, at a minimum, meet the standards described at 42 CFR 438.10. The notice of resolution includes at least the following items:

- The results of the resolution process and the date it was completed; and
- For appeals not resolved wholly in favor of the enrollees:
 - The right to request a State review, and how to do so.
 - The right to request and receive benefits while the hearing is pending, and how to make the request.
 - That the enrollee may, consistent with State policy, be held liable for the cost of those benefits if the hearing decision upholds the MCO's, PIHP's, or PAHP's adverse benefit determination. (42 CFR 457.1260, cross referencing to 42 CFR 457.408(d)(2)(i) and (e))

3.9.22 For notice of an expedited resolution, the State assures that each contracted MCO, PIHP, or PAHP makes reasonable efforts to provide oral notice, in addition to the written notice of resolution. (42 CFR 457.1260, cross referencing to 42 CFR 457.408(d)(2)(ii))

3.9.23 The State assures that if it offers an external medical review:

- The review is at the enrollee's option and is not required before or used as a deterrent to proceeding to the State review;
- The review is independent of both the State and MCO, PIHP, or PAHP; and
- The review is offered without any cost to the enrollee. (42 CFR 457.1260, cross-referencing to 42 CFR 438.408(f))

3.9.24 The State assures that MCOs, PIHPs, and PAHPs do not take punitive action against providers who request an expedited resolution or support an enrollee's appeal. (42 CFR 457.1260, cross-referencing to 42 CFR 438.410(b))

3.9.25 The State assures that MCOs, PIHPs, or PAHPs must provide information specified in 42 CFR 438.10(g)(2)(xi) about the grievance and appeal system to all providers and subcontractors at the time they enter into a contract. This includes:

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- The right to file grievances and appeals;
- The requirements and timeframes for filing a grievance or appeal;
- The availability of assistance in the filing process;
- The right to request a State review after the MCO, PIHP or PAHP has made a determination on an enrollee's appeal which is adverse to the enrollee; and
- The fact that, when requested by the enrollee, benefits that the MCO, PIHP, or PAHP seeks to reduce or terminate will continue if the enrollee files an appeal or a request for State review within the timeframes specified for filing, and that the enrollee may, consistent with State policy, be required to pay the cost of services furnished while the appeal or State review is pending if the final decision is adverse to the enrollee. (42 CFR 457.1260, cross-referencing to 42 CFR 438.414)

3.9.26 The State assures that it requires MCOs, PIHPs, and PAHPs to maintain records of grievances and appeals and reviews the information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy. The record must be accurately maintained in a manner accessible to the state and available upon request to CMS. (42 CFR 457.1260, cross-referencing to 42 CFR 438.416)

3.9.27 The State assures that if the MCO, PIHP, or PAHP, or the State review officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO, PIHP, or PAHP must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. (42 CFR 457.1260, cross-referencing to 42 CFR 438.424(a))

3.10 Program Integrity

Guidance: The State should complete Section 11 (Program Integrity) in addition to Section 3.10.

Guidance: Only States with MCOs, PIHPs, or PAHPs need to answer the first seven assurances (3.10.1 through 3.10.7).

3.10.1 The State assures that any entity seeking to contract as an MCO, PIHP, or PAHP under a separate child health program has administrative and management arrangements or procedures designed to safeguard against fraud and abuse, including:

- Enforcing MCO, PIHP, and PAHP compliance with all applicable Federal and State statutes, regulations, and standards;
- Prohibiting MCOs, PIHPs, or PAHPs from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of the MCO, PAHP, or PIHP for the purpose of influencing the individual to enroll with the entity; and
- Including a mechanism for MCOs, PIHPs, and PAHPs to report to the State, to CMS, or to the Office of Inspector General (OIG) as appropriate, information on violations of law by subcontractors, providers, or enrollees of an MCO, PIHP, or PAHP and other individuals. (42 CFR 457.1280)

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- 3.10.2** ☒ The State assures that it has in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to the MCO, PIHP, or PAHP contracts or enrollment processes described in 42 CFR 457.1210(a). (42 CFR 457.1214, cross referencing 42 CFR 438.58)
- 3.10.3** ☒ The State assures that it periodically, but no less frequently than once every 3 years, conducts, or contracts for the conduct of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, each MCO, PIHP or PAHP. (42 CFR 457.1285, cross referencing 42 CFR 438.602(e))
- 3.10.4** ☒ The State assures that it requires MCOs, PIHPs, PAHP, and or subcontractors (only to the extent that the subcontractor is delegated responsibility by the MCO, PIHP, or PAHP for coverage of services and payment of claims) implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. The arrangements or procedures must include the following:
- A compliance program that include all of the elements described in 42 CFR 438.608(a)(1);
 - Provision for prompt reporting of all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State;
 - Provision for prompt notification to the State when it receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility;
 - Provision for notification to the State when it receives information about a change in a network provider's circumstances that may affect the network provider's eligibility to participate in the managed care program, including the termination of the provider agreement with the MCO, PIHP or PAHP;
 - Provision for a method to verify, by sampling or other methods, whether services that have been represented to have been delivered by network providers were received by enrollees and the application of such verification processes on a regular basis;
 - In the case of MCOs, PIHPs, or PAHPs that make or receive annual payments under the contract of at least \$5,000,000, provision for written policies for all employees of the entity, and of any contractor or agent, that provide detailed information about the False Claims Act and other Federal and State laws described in section 1902(a)(68) of the Act, including information about rights of employees to be protected as whistleblowers;
 - Provision for the prompt referral of any potential fraud, waste, or abuse that the MCO, PIHP, or PAHP identifies to the State Medicaid/CHIP program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit; and
 - Provision for the MCO's, PIHP's, or PAHP's suspension of payments to a network provider for which the State determines there is a credible allegation of fraud in accordance with 42 CFR 455.23. (42 CFR 457.1285, cross referencing 42 CFR 438.608(a))
- 3.10.5** ☒ The State assures that each MCO, PIHP, or PAHP requires and has a mechanism for a network provider to report to the MCO, PIHP or PAHP when it has received an overpayment, to return the overpayment to the MCO, PIHP or PAHP within 60 calendar days after the date on which the overpayment was

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identified, and to notify the MCO, PIHP or PAHP in writing of the reason for the overpayment. (42 CFR 457.1285, cross referencing 42 CFR 438.608(d)(2))

- 3.10.6** The State assures that each MCO, PIHP, or PAHP reports annually to the State on their recoveries of overpayments. (42 CFR 457.1285, cross referencing 42 CFR 438.608(d)(3))
- 3.10.7** The State assures that it screens and enrolls, and periodically revalidates, all network providers of MCOs, PIHPs, and PAHPs, in accordance with the requirements of part 455, subparts B and E. This requirement also extends to PCCMs and PCCM entities to the extent that the primary care case manager is not otherwise enrolled with the State to provide services to fee-for-service beneficiaries. (42 CFR 457.1285, cross referencing 42 CFR 438.602(b)(1) and 438.608(b))
- [State \[Delaware\] is working to be compliant with these assurances by January 1, 2020](#)
- 3.10.8** The State assures that it reviews the ownership and control disclosures submitted by the MCO, PIHP, PAHP, PCCM or PCCM entity, and any subcontractors. (42 CFR 457.1285, cross referencing 42 CFR 438.602(c))
- [State \[Delaware\] is working to be compliant with these assurances by January 1, 2020](#)
- 3.10.9** The State assures that it confirms the identity and determines the exclusion status of the MCO, PIHP, PAHP, PCCM or PCCM entity, any subcontractor, as well as any person with an ownership or control interest, or who is an agent or managing employee of the MCO, PIHP, PAHP, PCCM or PCCM entity through routine checks of Federal databases. If the State finds a party that is excluded, the State promptly notifies the MCO, PIHP, PAHP, PCCM, or PCCM entity and takes action consistent with 42 CFR 438.610(c). (42 CFR 457.1285, cross referencing 42 CFR 438.602(d))
- [State \[Delaware\] is working to be compliant with these assurances by January 1, 2020](#)
- 3.10.10** The State assures that it receives and investigates information from whistleblowers relating to the integrity of the MCO, PIHP, PAHP, PCCM, or PCCM entity, subcontractors, or network providers receiving Federal funds under this part. (42 CFR 457.1285, cross referencing 42 CFR 438.602(f))
- 3.10.11** The State assures that MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities with which the State contracts are not located outside of the United States and that no claims paid by an MCO, PIHP, or PAHP to a network provider, out-of-network provider, subcontractor or financial institution located outside of the U.S. are considered in the development of actuarially sound capitation rates. (42 CFR 457.1285, cross referencing to 42 CFR 438.602(i); Section 1902(a)(80) of the Social Security Act)
- 3.10.12** The State assures that MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities submit to the State the following data, documentation, and information:
- Encounter data in the form and manner described in 42 CFR 438.818.

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- Data on the basis of which the State determines the compliance of the MCO, PIHP, or PAHP with the medical loss ratio requirement described in 42 CFR 438.8.
- Data on the basis of which the State determines that the MCO, PIHP or PAHP has made adequate provision against the risk of insolvency as required under 42 CFR 438.116.
- Documentation described in 42 CFR 438.207(b) on which the State bases its certification that the MCO, PIHP or PAHP has complied with the State's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in 42 CFR 438.206.
- Information on ownership and control described in 42 CFR 455.104 of this chapter from MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and subcontractors as governed by 42 CFR 438.230.
- The annual report of overpayment recoveries as required in 42 CFR 438.608(d)(3). (42 CFR 457.1285, cross referencing 42 CFR 438.604(a))

3.10.13 The State assures that:

- It requires that the data, documentation, or information submitted in accordance with 42 CFR 457.1285, cross referencing 42 CFR 438.604(a), is certified in a manner that the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's Chief Executive Officer or Chief Financial Officer is ultimately responsible for the certification. (42 CFR 457.1285, cross referencing 42 CFR 438.606(a))
- It requires that the certification includes an attestation that, based on best information, knowledge, and belief, the data, documentation, and information specified in 42 CFR 438.604 are accurate, complete, and truthful. (42 CFR 457.1285, cross referencing 42 CFR 438.606(b)); and
- It requires the MCO, PIHP, PAHP, PCCM, or PCCM entity to submit the certification concurrently with the submission of the data, documentation, or information required in 42 CFR 438.604(a) and (b). (42 CFR 457.1285, cross referencing 42 CFR 438.604(c))

3.10.14 The State assures that each MCO, PIHP, PAHP, PCCM, PCCM entity, and any subcontractors provides: written disclosure of any prohibited affiliation under 42 CFR 438.610, written disclosure of and information on ownership and control required under 42 CFR 455.104, and reports to the State within 60 calendar days when it has identified the capitation payments or other payments in excess of amounts specified in the contract. (42 CFR 457.1285, cross referencing 42 CFR 438.608(c))

3.10.15 The State assures that services are provided in an effective and efficient manner. (Section 2101(a))

3.10.16 The State assures that it operates a Web site that provides:

- The documentation on which the State bases its certification that the MCO, PIHP or PAHP has complied with the State's requirements for availability and accessibility of services;
- Information on ownership and control of MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and subcontractors; and
- The results of any audits conducted under 42 CFR 438.602(e). (42 CFR 457.1285, cross-referencing to 42 CFR 438.602(g)).

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3.11 Sanctions

Guidance: Only States with MCOs need to answer the next three assurances (3.11.1 through 3.11.3).

Intermediate sanctions are defined at 42 CFR 438.702(a)(4) as: (1) Civil money penalties; (2) Appointment of temporary management (for an MCO); (3) Granting enrollees the right to terminate enrollment without cause; (4) Suspension of all new enrollment; and (5) Suspension of payment for beneficiaries.

- 3.11.1 The State assures that it has established intermediate sanctions that it may impose if it makes the determination that an MCO has acted or failed to act in a manner specified in 438.700(b)-(d). (42 CFR 457.1270, cross referencing 42 CFR 438.700)
- 3.11.2 The State assures that it will impose temporary management if it finds that an MCO has repeatedly failed to meet substantive requirements of part 457 subpart L. (42 CFR 457.1270, cross referencing 42 CFR 438.706(b))
- 3.11.3 The State assures that if it imposes temporary management on an MCO, the State allows enrollees the right to terminate enrollment without cause and notifies the affected enrollees of their right to terminate enrollment. (42 CFR 457.1270, cross referencing 42 CFR 438.706(b))

Guidance: Only states with PCCMs, or PCCM entities need to answer the next assurance (3.11.4).

- 3.11.4 Does the State establish intermediate sanctions for PCCMs or PCCM entities?
- Yes
- No

Guidance: Only states with MCOs and states that answered yes to assurance 3.11.4 need to complete the next three assurances (3.11.5 through 3.11.7).

- 3.11.5 The State assures that before it imposes intermediate sanctions, it gives the affected entity timely written notice. (42 CFR 457.1270, cross referencing 42 CFR 438.710(a))
- 3.11.6 The State assures that if it intends to terminate an MCO, PCCM, or PCCM entity, it provides a pre-termination hearing and written notice of the decision as specified in 42 CFR 438.710(b). If the decision to terminate is affirmed, the State assures that it gives enrollees of the MCO, PCCM or PCCM entity notice of the termination and information, consistent with 42 CFR 438.10, on their options for receiving CHIP services following the effective date of termination. (42 CFR 457.1270, cross referencing 42 CFR 438.710(b))
- 3.11.7 The State assures that it will give CMS written notice that complies with 42 CFR 438.724 whenever it imposes or lifts a sanction for one of the violations listed in 42 CFR 438.700. (42 CFR 457.1270, cross referencing 42 CFR 438.724)

3.12 Quality Measurement and Improvement; External Quality Review

Guidance: The State should complete Sections 7 (Quality and Appropriateness of Care) and 9 (Strategic Objectives and Performance Goals and Plan Administration) in addition to Section 3.12.

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Guidance: States with MCO(s), PIHP(s), PAHP(s), or certain PCCM entity/ies (PCCM entities whose contract with the State provides for shared savings, incentive payments or other financial reward for improved quality outcomes - see 42 CFR 457.1240(f)) - should complete the applicable sub-sections for each entity type in this section, regarding 42 CFR 457.1240 and 1250.

3.12.1 Quality Strategy

Guidance: All states with MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities need to complete section 3.12.1.

- 3.12.1.1** The State assures that it will draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished CHIP enrollees as described in 42 CFR 438.340(a). The quality strategy must include the following items:
- The State-defined network adequacy and availability of services standards for MCOs, PIHPs, and PAHPs required by 42 CFR 438.68 and 438.206 and examples of evidence-based clinical practice guidelines the State requires in accordance with 42 CFR 438.236;
 - A description of:
 - The quality metrics and performance targets to be used in measuring the performance and improvement of each MCO, PIHP, and PAHP with which the State contracts, including but not limited to, the performance measures reported in accordance with 42 CFR 438.330(c); and
 - The performance improvement projects to be implemented in accordance with 42 CFR 438.330(d), including a description of any interventions the State proposes to improve access, quality, or timeliness of care for beneficiaries enrolled in an MCO, PIHP, or PAHP;
 - Arrangements for annual, external independent reviews, in accordance with 42 CFR 438.350, of the quality outcomes and timeliness of, and access to, the services covered under each contract;
 - A description of the State's transition of care policy required under 42 CFR 438.62(b)(3);
 - The State's plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, and primary language;
 - For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of 42 CFR Part 438;
 - A description of how the State will assess the performance and quality outcomes achieved by each PCCM entity;
 - The mechanisms implemented by the State to comply with 42 CFR 438.208(c)(1) (relating to the identification of persons with special health care needs);
 - Identification of the external quality review (EQR)-related activities for which the State has exercised the option under 42 CFR 438.360 (relating to nonduplication of EQR-related activities), and explain the rationale for the State's determination that the private accreditation activity is comparable to such EQR-related activities;

- Identification of which quality measures and performance outcomes the State will publish at least annually on the Web site required under 42 CFR 438.10(c)(3); and
 - The State's definition of a "significant change" for the purposes of updating the quality strategy under 42 CFR 438.340(c)(3)(ii). (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(b))
- 3.12.1.2** ☒ The State assures that the goals and objectives for continuous quality improvement in the quality strategy are measurable and take into consideration the health status of all populations in the State served by the MCO, PIHP, and PAHP. (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(b)(2))
- 3.12.1.3** ☒ The State assures that for purposes of the quality strategy, the State provides the demographic information for each CHIP enrollee to the MCO, PIHP or PAHP at the time of enrollment. (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(b)(6))
- 3.12.1.4** ☒ The State assures that it will review and update the quality strategy as needed, but no less than once every 3 years. (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(c)(2))
- 3.12.1.5** ☒ The State assures that its review and updates to the quality strategy will include an evaluation of the effectiveness of the quality strategy conducted within the previous 3 years and the recommendations provided pursuant to 42 CFR 438.364(a)(4). (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(c)(2)(i) and (iii)).
- 3.12.1.6** ☒ The State assures that it will submit to CMS:
- A copy of the initial quality strategy for CMS comment and feedback prior to adopting it in final; and
 - A copy of the revised strategy whenever significant changes are made to the document, or whenever significant changes occur within the State's CHIP program, including after the review and update required every 3 years. (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(c)(3))
- 3.12.1.7** ☒ Before submitting the strategy to CMS for review, the State assures that when it drafts or revises the State's quality strategy it will:
- Make the strategy available for public comment; and
 - If the State enrolls Indians in the MCO, PIHP, or PAHP, consult with Tribes in accordance with the State's Tribal consultation policy. (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(c)(1))
- 3.12.1.8** ☒ The State assures that it makes the results of the review of the quality strategy (including the effectiveness evaluation) and the final quality strategy available on the Web site required under 42 CFR 438.10(c)(3). (42 CFR 457.1240(e), cross referencing to 42 CFR 438.340(c)(2)(ii) and (d))

3.12.2 Quality Assessment and Performance Improvement Program

3.12.2.1 Quality Assessment and Performance Improvement Program: Measures and Projects

Guidance: Only states with MCOs, PIHPs, or PAHPs need to complete the next two assurances (3.12.2.1.1 and 3.12.2.1.2).

- 3.12.2.1.1** The State assures that it requires that each MCO, PIHP, and PAHP establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees as provided in 42 CFR 438.330, except that the terms of 42 CFR 438.330(d)(4) (related to dual eligibles) do not apply. The elements of the assessment and program include at least:
- Standard performance measures specified by the State;
 - Any measures and programs required by CMS (42 CFR 438.330(a)(2));
 - Performance improvement projects that focus on clinical and non-clinical areas, as specified in 42 CFR 438.330(d);
 - Collection and submission of performance measurement data in accordance with 42 CFR 438.330(c);
 - Mechanisms to detect both underutilization and overutilization of services; and
 - Mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs, as defined by the State in the quality strategy under 42 CFR 457.1240(e) and Section 3.12.1 of this template). (42 CFR 457.1240(b), cross referencing to 42 CFR 438.330(b) and (c)(1))

Guidance: A State may request an exemption from including the performance measures or performance improvement programs established by CMS under 42 CFR 438.330(a)(2), by submitting a written request to CMS explaining the basis for such request.

- 3.12.2.1.2** The State assures that each MCO, PIHP, and PAHP's performance improvement projects are designed to achieve significant improvement, sustained over time, in health outcomes and enrollee satisfaction. The performance improvement projects include at least the following elements:
- Measurement of performance using objective quality indicators;
 - Implementation of interventions to achieve improvement in the access to and quality of care;
 - Evaluation of the effectiveness of the interventions based on the performance measures specified in 42 CFR 438.330(d)(2)(i); and
 - Planning and initiation of activities for increasing or sustaining improvement. (42 CFR 457.1240(b), cross referencing to 42 CFR 438.330(d)(2))

Guidance: Only states with a PCCM entity whose contract with the State provides for shared savings, incentive payments or other financial reward for improved quality outcomes need to, complete the next assurance (3.12.2.1.3).

- 3.12.2.1.3** The State assures that it requires that each PCCM entity establishes and implements an ongoing comprehensive quality assessment and performance improvement program for the

services it furnishes to its enrollees as provided in 42 CFR 438.330, except that the terms of 42 CFR 438.330(d)(4) (related to dual eligibles) do not apply. The assessment and program must include:

- Standard performance measures specified by the State;
- Mechanisms to detect both underutilization and overutilization of services; and
- Collection and submission of performance measurement data in accordance with 42 CFR 438.330(c). (42 CFR 457.1240(a) and (b), cross referencing to 42 CFR 438.330(b)(3) and (c))

3.12.2.2 Quality Assessment and Performance Improvement Program: Reporting and Effectiveness

Guidance: Only states with MCOs, PIHPs, or PAHPs need to complete Section 3.12.2.2.

3.12.2.2.1 The State assures that each MCO, PIHP, and PAHP reports on the status and results of each performance improvement project conducted by the MCO, PIHP, and PAHP to the State as required by the State, but not less than once per year. (42 CFR 457.1240(b), cross referencing to 42 CFR 438.330(d)(3))

3.12.2.2.2 The State assures that it annually requires each MCO, PIHP, and PAHP to:

- 1) Measure and report to the State on its performance using the standard measures required by the State;
- 2) Submit to the State data specified by the State to calculate the MCO's, PIHP's, or PAHP's performance using the standard measures identified by the State; or
- 3) Perform a combination of options (1) and (2) of this assurance. (42 CFR 457.1240(b), cross referencing to 42 CFR 438.330(c)(2))

3.12.2.2.3 The State assures that the State reviews, at least annually, the impact and effectiveness of the quality assessment and performance improvement program of each MCO, PIHP, PAHP and PCCM entity. The State's review must include:

- The MCO's, PIHP's, PAHP's, and PCCM entity's performance on the measures on which it is required to report; and
- The outcomes and trended results of each MCO's, PIHP's, and PAHP's performance improvement projects. (42 CFR 457.1240(b), cross referencing to 42 CFR 438.330(e)(1))

3.12.3 Accreditation

Guidance: Only states with MCOs, PIHPs, or PAHPs need to complete Section 3.12.3.

3.12.3.1 The State assures that it requires each MCO, PIHP, and PAHP to inform the state whether it has been accredited by a private independent accrediting entity, and, if the MCO, PIHP, or PAHP has received accreditation by a private independent accrediting agency, that the MCO,

PIHP, and PAHP authorizes the private independent accrediting entity to provide the State a copy of its recent accreditation review that includes the MCO, PIHP, and PAHP's accreditation status, survey type, and level (as applicable); accreditation results, including recommended actions or improvements, corrective action plans, and summaries of findings; and expiration date of the accreditation. (42 CFR 457.1240(c), cross referencing to 42 CFR 438.332(a) and (b)).

- 3.12.3.2** The State assures that it will make the accreditation status for each contracted MCO, PIHP, and PAHP available on the Web site required under 42 CFR 438.10(c)(3), including whether each MCO, PIHP, and PAHP has been accredited and, if applicable, the name of the accrediting entity, accreditation program, and accreditation level; and update this information at least annually. (42 CFR 457.1240(c), cross referencing to 42 CFR 438.332(c))

3.12.4 Quality Rating

Guidance: Only states with MCOs, PIHPs, or PAHPs need to complete Section 3.12.4.

- The State assures that it will implement and operate a quality rating system that issues an annual quality rating for each MCO, PIHP, and PAHP, which the State will prominently display on the Web site required under 42 CFR 438.10(c)(3), in accordance with the requirements set forth in 42 CFR 438.334. (42 CFR 457.1240(d))

Guidance: States will be required to comply with this assurance within 3 years after CMS, in consultation with States and other Stakeholders and after providing public notice and opportunity for comment, has identified performance measures and a methodology for a Medicaid and CHIP managed care quality rating system in the Federal Register.

3.12.5 Quality Review

Guidance: All states with MCOs, PIHPs, PAHPs, PCCMs or PCCM entities need to complete Sections 3.12.5 and 3.12.5.1.

- The State assures that each contract with a MCO, PIHP, PAHP, or PCCM entity requires that a qualified EQRO performs an annual external quality review (EQR) for each contracting MCO, PIHP, PAHP or PCCM entity, except as provided in 42 CFR 438.362. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.350(a))

3.12.5.1 External Quality Review Organization

- 3.12.5.1.1** The State assures that it contracts with at least one external quality review organization (EQRO) to conduct either EQR alone or EQR and other EQR-related activities. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.356(a))
- 3.12.5.1.2** The State assures that any EQRO used by the State to comply with 42 CFR 457.1250 must meet the competence and independence requirements of 42 CFR 438.354 and, if the EQRO uses subcontractors, that the EQRO is accountable for and oversees all subcontractor functions. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.354 and 42 CFR 438.356(b) through (d))

3.12.5.2 External Quality Review-Related Activities

Guidance: Only states with MCOs, PIHPs, or PAHPs need to complete the next three assurances (3.12.5.2.1 through 3.12.5.2.3). Under 42 CFR 457.1250(a), the State, or its agent or EQRO, must conduct the EQR-related activity under 42 CFR 438.358(b)(1)(iv) regarding validation of the MCO, PIHP, or PAHP's network adequacy during the preceding 12 months; however, the State may permit its contracted MCO, PIHP, and PAHPs to use information from a private accreditation review in lieu of any or all the EQR-related activities under 42 CFR 438.358(b)(1)(i) through (iii) (relating to the validation of performance improvement projects, validation of performance measures, and compliance review).

- 3.12.5.2.1** The State assures that the mandatory EQR-related activities described in 42 CFR 438.358(b)(1)(i) through (iv) (relating to the validation of performance improvement projects, validation of performance measures, compliance review, and validation of network adequacy) will be conducted on all MCOs, PIHPs, or PAHPs. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.358(b)(1))
- 3.12.5.2.2** The State assures that if it elects to use nonduplication for any or all of the three mandatory EQR-related activities described at 42 CFR 438.358(b)(1)(i) – (iii), the State will document the use of nonduplication in the State's quality strategy. (42 CFR 457.1250(a), cross referencing 438.360, 438.358(b)(1)(i) through (b)(1)(iii), and 438.340)
- 3.12.5.2.3** The State assures that if the State elects to use nonduplication for any or all of the three mandatory EQR-related activities described at 42 CFR 438.358(b)(1)(i) – (iii), the State will ensure that all information from a Medicare or private accreditation review for an MCO, PIHP, or PAHP will be furnished to the EQRO for analysis and inclusion in the EQR technical report described in 42 CFR 438.364. ((42 CFR 457.1250(a), cross referencing to 42 CFR 438.360(b))

Guidance: Only states with PCCM entities need to complete the next assurance (3.12.5.2.4).

- 3.12.5.2.4** The State assures that the mandatory EQR-related activities described in 42 CFR 438.358(b)(2) (cross-referencing 42 CFR 438.358(b)(1)(ii) and (b)(1)(iii)) will be conducted on all PCCM entities, which include:
- Validation of PCCM entity performance measures required in accordance with 42 CFR 438.330(b)(2) or PCCM entity performance measures calculated by the State during the preceding 12 months; and
 - A review, conducted within the previous 3-year period, to determine the PCCM entity's compliance with the standards set forth in subpart D of 42 CFR part 438 and the quality assessment and performance improvement requirements described in 42 CFR 438.330. (42 CFR 457.1250(a), cross referencing to 438.358(b)(2))

3.12.5.3 External Quality Review Report

Guidance: All states with MCOs, PIHPs, PAHPs, PCCMs or PCCM entities need to complete Sections 3.12.5.3.

- 3.12.5.3.1** The State assures that data obtained from the mandatory and optional, if applicable, EQR-related activities in 42 CFR 438.358 is used for the annual EQR to comply with 42 CFR 438.350 and must include, at a minimum, the elements in §438.364(a)(2)(i) through (iv). (42 CFR 457.1250(a), cross referencing to 42 CFR 438.358(a)(2))
- 3.12.5.3.2** The State assures that only a qualified EQRO will produce the EQR technical report (42 CFR 438.364(c)(1)).
- 3.12.5.3.3** The State assures that in order for the qualified EQRO to perform an annual EQR for each contracting MCO, PIHP, PAHP or PCCM entity under 42 CFR 438.350(a) that the following conditions are met:
- The EQRO has sufficient information to use in performing the review;
 - The information used to carry out the review must be obtained from the EQR-related activities described in 42 CFR 438.358 and, if applicable, from a private accreditation review as described in 42 CFR 438.360;
 - For each EQR-related activity (mandatory or optional), the information gathered for use in the EQR must include the elements described in 42 CFR 438.364(a)(2)(i) through (iv); and
 - The information provided to the EQRO in accordance with 42 CFR 438.350(b) is obtained through methods consistent with the protocols established by the Secretary in accordance with 42 CFR 438.352. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.350(b) through (e))
- 3.12.5.3.4** The State assures that the results of the reviews performed by a qualified EQRO of each contracting MCO, PIHP, PAHP, and PCCM entity are made available as specified in 42 CFR 438.364 in an annual detailed technical report that summarizes findings on access and quality of care. The report includes at least the following items:
- A description of the manner in which the data from all activities conducted in accordance with 42 CFR 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO, PIHP, PAHP, or PCCM entity (described in 42 CFR 438.310(c)(2));
 - For each EQR-related activity (mandatory or optional) conducted in accordance with 42 CFR 438.358:
 - Objectives;
 - Technical methods of data collection and analysis;
 - Description of data obtained, including validated performance measurement data for each activity conducted in

- accordance with 42 CFR 438.358(b)(1)(i) and (ii); and
 - Conclusions drawn from the data;
 - An assessment of each MCO's, PIHP's, PAHP's, or PCCM entity's strengths and weaknesses for the quality, timeliness, and access to health care services furnished to CHIP beneficiaries;
 - Recommendations for improving the quality of health care services furnished by each MCO, PIHP, PAHP, or PCCM entity, including how the State can target goals and objectives in the quality strategy, under 42 CFR 438.340, to better support improvement in the quality, timeliness, and access to health care services furnished to CHIP beneficiaries;
 - Methodologically appropriate, comparative information about all MCOs, PIHPs, PAHPs, and PCCM entities, consistent with guidance included in the EQR protocols issued in accordance with 42 CFR 438.352(e); and
 - An assessment of the degree to which each MCO, PIHP, PAHP, or PCCM entity has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.350(f) and 438.364(a))
- 3.12.5.3.5** The State assures that it does not substantively revise the content of the final EQR technical report without evidence of error or omission. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(b))
- 3.12.5.3.6** The State assures that it finalizes the annual EQR technical report by April 30th of each year. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(c)(1))
- 3.12.5.3.7** The State assures that it posts the most recent copy of the annual EQR technical report on the Web site required under 42 CFR 438.10(c)(3) by April 30th of each year. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(c)(2)(i))
- 3.12.5.3.8** The State assures that it provides printed or electronic copies of the information specified in 42 CFR 438.364(a) for the annual EQR technical report, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, PAHP, or PCCM, beneficiary advocacy groups, and members of the general public. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(c)(2)(ii))
- 3.12.5.3.9** The State assures that it makes the information specified in 42 CFR 438.364(a) for the annual EQR technical report available in alternative formats for persons with disabilities, when requested. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(c)(3))
- 3.12.5.3.10** The State assures that information released under 42 CFR 438.364 for the annual EQR technical report does not disclose the identity or other protected health information of any

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patient. (42 CFR 457.1250(a), cross referencing to 42 CFR 438.364(d))