



DATE: January 25, 2012

TO: Organizations Interested in Offering Capitated Financial Alignment Demonstration Plans in Interested States

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SUBJECT: Guidance for Organizations Interested in Offering Capitated Financial Alignment Demonstration Plans

I. Background

Since its creation in 2010, the Medicare-Medicaid Coordination Office (MMCO) has been working to improve the quality of care that individuals dually eligible for Medicare and Medicaid (Medicare-Medicaid enrollees) receive by expanding access to seamless, integrated programs. In July 2011, the MMCO announced a new opportunity for States to participate in demonstration projects to align financing between Medicare and Medicaid to support improvements in the quality and cost of care for Medicare-Medicaid enrollees (please refer to our July 8, 2011 State Medicaid Director (SMD) letter at http://www.cms.gov/smdl/downloads/Financial_Models_Supporting_Integrated_Care_SMD.pdf for more information). Through the Center for Medicare & Medicaid Innovation (the Innovation Center), CMS will test two financial alignment models with States across the country – a capitated approach and a managed fee-for-service approach. The capitated model that will use health plans or other qualified entities¹ for delivery of medical, behavioral health, and long-term services and supports is the subject of the information in this guidance.

Under the capitated financial alignment demonstrations, CMS will work with interested States to combine Medicare and Medicaid authorities to test a new payment and service delivery model to reduce program expenditures under Medicare and Medicaid, while enhancing the quality of care furnished to Medicare-Medicaid enrollees. Demonstrations under this program will last three years, and our goal is to approve demonstration proposals and finalize demonstration plan selection in order to effectuate enrollments in 2013. All demonstrations will include a rigorous evaluation, the results of which will help inform the potential for future program changes.

Under these demonstrations, CMS, the State, and health plans or other qualified entities will enter into a three-way contract. The finalization of each contract will follow a joint plan selection process by CMS and each participating State. The three-way contracts will test administrative, benefit and enrollment

¹ Health plans or other qualified entities are referred to as “interested organizations” throughout this document.

flexibilities that will further the goal of providing a seamless experience for Medicare-Medicaid enrollees by utilizing a simplified and unified set of rules and an integrated payment model.

This guidance document includes more information about the demonstration, including:

- Payment Principles. Section II summarizes key information about how prospective capitated payment rates for health plans will be developed for the provision of an integrated benefit package for the full continuum of Medicare and Medicaid benefits to Medicare-Medicaid enrollees. It also outlines how savings will be achieved for both the Medicare and Medicaid programs.
- Standards in Key Programmatic Areas. Section III and Appendix 1 of this document summarize information about key programmatic areas under the demonstration in the context of current Medicare and Medicaid requirements in those areas. We note, in particular, that Medicare prescription drug (Part D) requirements will be applicable under the demonstration.
- State Demonstration Approval Process Key Dates. Section IV summarizes the key steps in the submission, review, and approval of State demonstration proposals, a process that will overlap with – but proceed separately from – the joint plan selection process. Given our goal of effectuating enrollments in demonstration plans in 2013, we note that the steps associated with State demonstration approvals will, in many cases, occur concurrently with the demonstration plan selection process, which is described in more detail in Section V of this guidance.
- Plan Selection Process Key Dates. Section V details key dates for interested organizations to provide the necessary context to inform their decisions about participation in this initiative. Interested organizations must be prepared to meet the timelines articulated in Section V in order to be selected as plans under demonstrations with effective enrollment dates of January 1, 2013.

Because this demonstration is combining Medicare and Medicaid authorities to provide integrated delivery of benefits, the joint plan selection will require that such organizations meet State-specific requirements, including a combination of Medicare, Medicaid and integrated requirements (some of which are described in this guidance). To be selected to participate in the demonstration, interested organizations will need to demonstrate their capacity to meet all requirements.

CMS is committed to providing the necessary information and training to States and all interested organizations, regardless of their previous level of experience in contracting with Medicare. Included in this guidance is background information on contracting and application timelines in the underlying Medicare program to provide context for certain timing and other flexibilities that will be available to plans interested in participating in the demonstration.

We also emphasize that organizations that are currently offering or intend to offer non-demonstration Medicare Advantage (MA) or Prescription Drug Plan (PDP) products in 2013 will need to proceed with application and plan approval processes for those products separately from the process for plan selection under the demonstrations.

- Instructions for Submitting a Notice of Intent to Participate as a Demonstration Plan. Section VI contains technical instructions for interested organizations. This notice of intent to apply (NOIA) process is non-binding, but it is a necessary step for any interested organization. Therefore, we encourage any interested organization to participate in this process consistent with demonstration planning underway in each State. While interested organizations may submit a NOIA earlier, an interested organization that does not meet the **April 2, 2012** NOIA submission deadline will not be permitted to operate a demonstration plan in 2013.
- Network Adequacy Determinations. Section VII introduces the process whereby interested organizations will demonstrate network adequacy under the demonstration, including the Medicare network adequacy requirements. We also outline the process whereby interested organizations may seek exceptions from Medicare network adequacy standards for non-drug medical services.

Interested organizations will be required to follow the instructions provided in this guidance in order to effectuate enrollments in 2013. We note that, in addition to the requirements described in this guidance, plans must also qualify for participation based on each State's specific plan selection process, which will be developed based in part on feedback received through various State stakeholder outreach processes currently underway.

CMS will provide more detailed guidance both to States and interested organizations between February and early April 2012. Any questions related to demonstration timelines and requirements should be sent to CMS MMCOcapsmodel@cms.hhs.gov.

II. Payment Principles

Under the capitated financial alignment demonstration, CMS and a participating State will enter into a three-way contract with selected health plans to provide the full range of Medicare and Medicaid benefits to Medicare-Medicaid enrollees in the demonstration areas. Participating plans will receive a capitation rate that will reflect the integrated delivery of the full continuum of Medicare and Medicaid benefits for Medicare-Medicaid enrollees. This new payment model will:

- Align incentives;
- Provide plans with flexibility; and
- Improve quality of and access to health care services for enrollees.

Rates for participating organizations will be developed by CMS in partnership with each State based on baseline spending in both programs and anticipated savings that will result from integration and improved care management. The Part D portion of the capitation rate will be based on the standardized national average bid amount that will be risk adjusted in accordance with the rules that apply to all other Part D plans.

The rate will provide upfront savings to both CMS and the State. Absent savings for both payers, the demonstration will not go forward. CMS and its Office of the Actuary (OACT) will work together with the State and its actuaries to determine the portion of the capitated payment paid by CMS (for Medicare) and the State (for Medicaid).

III. Standards in Key Programmatic Areas

A. General Information

Over the last several months, MMCO has been working closely with the Center for Medicare, the Center for Medicaid and CHIP Services, and the Innovation Center to develop additional policy and operational detail for the capitated financial alignment demonstrations. In mid-December, we provided additional detail to States interested in pursuing the capitated financial alignment model. Appendix 1 includes summaries of key programmatic areas for the demonstration that will be further defined in the Memorandum of Understanding (MOU) negotiated between States and CMS (a draft template of which was provided in our July 8, 2011 SMD letter) and the three-way contract, and that will serve as a tool that we will use to work with States to build out State-specific details associated with their individual demonstrations. The chart in Appendix 1 summarizes Medicare and Medicaid requirements in these key programmatic areas and the pre-established parameter and/or preferred requirement standard in each area. Pre-established parameters are those demonstration parameters that have been determined and were announced in the MOU template that was released in the July 8, 2011 SMD letter. Preferred standards are CMS' starting point for the framework to be utilized under the State demonstrations and will be discussed in more detail with States as part of their demonstration and MOU development and approval processes.

B. Part D Requirements

As detailed in Appendix 1, Medicare Part D requirements – including with respect to specific benefits and cost-sharing, network adequacy, formularies, and submission of prescription drug event data – will be applicable to demonstration plans. Interested organizations should therefore begin to prepare for the submission (either by themselves or in partnership with a Pharmacy Benefit Manager, or PBM) of critical Part D requirements, including a formulary, a Medication Therapy Management Program (MTMP), a Part D pharmacy network, and a plan benefit package. We provide additional resources for information about Part D requirements in Appendix 1 and intend to provide training on these and other Medicare requirements to interested organizations to ensure they have the tools they need to successfully navigate the plan selection process.

IV. State Demonstration Approval Process Key Dates

Following is a summary of the steps associated with submission, approval, and review of State demonstration proposals. State-specific timelines will be developed for each demonstration proposal; the dates below identify the general sequencing of the demonstration development and approval processes. Given our goal of effectuating enrollment in demonstration plans in 2013, we note that these steps will in many cases occur concurrently with the demonstration plan selection process, which is described in more detail in Section V of this guidance.

1. **State Letter of Intent (October 2011):** States interested in pursuing either of the two financial alignment models were required to submit Letters of Intent (LOIs) to CMS by October 1, 2011. Thirty-eight States and the District of Columbia submitted LOIs. Currently, we estimate that approximately 26 States are still exploring a capitated demonstration; for more information about this subset of States, please refer to the Notice of Intent to Apply questions in Appendix 2. For State-specific information, please refer to information shared by individual States about their demonstration plans.

2. **State Planning & Design Process (October 2011 – ongoing)**: For those States that determine they would like to pursue a demonstration, the LOI and initial dialogue with CMS initiate a comprehensive planning and design process. States are required to work with stakeholders during both the design process and implementation (for those States that ultimately implement).
3. **Demonstration Proposal (Spring – Summer 2012)**: The design process will culminate in a State demonstration proposal to CMS. Upon submission (following a 30-day public notice period), CMS will evaluate each proposal to determine whether it has met the CMS established standards and conditions before the State can enter into negotiation of a formal Memorandum of Understanding (MOU) with CMS.
4. **Memorandum of Understanding (Summer - Fall 2012)**: Once it has been determined that a proposal has met the standards and conditions, CMS will notify the State and then work with States to develop a State-specific MOU based on the templates provided as part of the July 8, 2011 SMD letter.
5. **Three-Way Contract (by mid-September 2012)**: Following approval of the MOU, States pursuing the capitated model would undergo a process with CMS to select qualified health plans that will result in a three-way contract among CMS, the State, and health plans or other qualified entities.

V. Plan Selection Process Key Dates

Demonstration plans will ultimately be selected through a joint CMS-State plan selection process that will utilize state-based plan selection vehicles. While the Medicare plan requirements described in guidance are necessary for interested plans to establish readiness for participation in the demonstration, plans will ultimately have to qualify for participation through each State's specific plan selection process. In other words, while interested organizations will be required to follow the instructions provided in this guidance, these instructions are merely part of the process of establishing qualification for the demonstrations and should not be seen as conflicting with or undermining State-specific requirements that are currently being established.

This section details key dates for organizations interested in participating in the demonstration, as well as background on the standard Medicare Advantage (MA) and Prescription Drug Plan (PDP) application processes and timelines in order to provide the necessary context to inform interested organizations' decisions about participation in this initiative. We also describe the flexibilities that will be provided to interested organizations vis-à-vis the standard Medicare timelines. In order to ensure a seamless transition and minimize disruption and confusion for Medicare-Medicaid enrollees enrolling in demonstration plans, CMS will leverage Medicare processes and related timelines in the plan selection process under the demonstrations. Use of these timelines and processes will also be important for creating operational efficiencies for effectuating enrollments in 2013. Interested organizations should understand that we have already created flexibilities where possible, and demonstration applicants must meet the established deadlines in order to participate as a demonstration plan in 2013.

CMS and States expect to work in partnership with interested organizations that have experience in coordinating and delivering care to Medicare-Medicaid enrollees, including current Medicare contractors offering Special Needs Plans (SNPs), State Medicaid managed care contractors, and other qualified organizations. We recognize the need for extensive technical assistance on Medicare-related

requirements and processes, particularly for interested organizations with no previous contracting experience with the Medicare program, and we are committed to partnering with States and providing this assistance to interested organizations following the release of this guidance.

A. Background on Standard Medicare Advantage (MA) and Prescription Drug Plan (PDP) Application and Contracting Cycles

This demonstration will test an integrated program that will have its own unique requirements, while using many pre-established State and CMS processes and requirements as a starting point. Although we will provide some flexibility, as described in Section V.B., for plans selected to participate in this demonstration, it is essential that interested organizations understand the standard MA and PDP application and contracting cycles. It is worth noting that organizations interested in offering non-demonstration plans in the 2013 contract year must continue to follow the standard MA and PDP timeline described below. Major payment, policy, and operational guidance necessary for interested organization to successfully bid for the upcoming contract year is generally provided through the advance and final payment notices and the Parts C and D Call Letter process (please refer to <http://www.cms.gov/MedicareAdvtgSpecRateStats/AD/list.asp>, <http://www.cms.gov/PrescriptionDrugCovContra/>, and <http://www.cms.gov/HealthPlansGenInfo/> for previous advance and final rate notices, as well as draft and final Call Letters). Each year, the advance payment notice and draft call letter are released for public comment in mid-February, and the final payment notice and final call letter are released in early April. Key milestones in the standard annual MA and PDP application and plan approval process are detailed below:

- November: Organizations interested offering new MA or PDP products, or expanding current MA and PDP service area(s), are required to express their intent to submit an application through a non-binding Notice of Intent to Apply (NOIA). Submission of a NOIA enables CMS to provide applicants with a provisional contract number, as well as the necessary access to CMS systems for purposes of submitting applications, bids, plan benefit packages, formularies, models of care, etc.
- Early January: MA and PDP applications for the following contract year are made available. Please note that MA plans offering prescription drug coverage (MA-PD plans) must submit both an MA and Part D application.
- Late February: Applications are due. Applications include submissions of network adequacy, State licensure, and – for special needs plans (SNPs) – models of care for review and approval by the National Committee for Quality Assurance (NCQA). Applications are reviewed between late February and mid-May.
- April: For organizations offering Part D benefits, Medication Therapy Management Program (MTMP) submissions and formularies are due. Formularies and MTMPs are reviewed between mid-April and July.^{2 3}

² As provided under 42 CFR 423.120(b) and in Chapter 6 of the Prescription Drug Benefit Manual (refer to <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf>), a Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet requirements for the following:

- First Monday in June: Plans prepare their bids and plan benefit package submissions for CMS review. These submissions are reviewed in June and July.
- Mid-September: All contracts are finalized and signed.
- Mid-September to early October: Roll-out of information about all available Medicare health plans, including via the *Medicare & You* handbook and the Medicare Plan Finder tool on www.medicare.gov.
- October 1 – Plans may begin marketing plan benefits and information for the upcoming contract year.
- October 15 – December 7 – Annual Coordinated Election Period.
- January 1 – Beneficiary elections made during the Annual Coordinated Election Period are effective.

B. Calendar of Key Dates for Medicare Requirements Portion of the Demonstration Plan Selection Process

Summarized below are the key dates for demonstration plan approval for the 2013 contract year. Our primary focus in this section is on the Medicare-specific requirements that interested organizations will need to satisfy to operate as demonstration plans; however, we remind interested organizations that there will also be State-specific requirements that must be satisfied as part of the joint plan selection process. Those requirements will be further detailed in State demonstration proposals and in the MOU negotiations.

This timeline details the timing and other flexibilities interested organizations will have relative to the standard MA and Part D application and contracting cycles. Such flexibility includes the deadline for submitting the non-binding plan Notice of Intent to Apply (NOIA) and plan formularies. We also expect to provide flexibility in the timelines for submitting information about State licensure, network adequacy, and plan models of care. Other submission deadlines will be the same for interested organizations as they are for organizations offering non-demonstration MA plans and PDPs – specifically,

Pharmacy and Therapeutics committee; provision of an adequate formulary; a transition process; limitation on changes in therapeutic classification; provision of notice regarding formulary changes; limitation of formulary changes prior to beginning of contract year; provider and patient education; and formulary changes during the contract year.

³ As provided under 42 CFR 423.153(d) and in Chapter 7 of the Prescription Drug Benefit Manual (refer to <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf>), a Part D sponsor must establish an MTMP that is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries (those that have multiple chronic conditions, are taking multiple Part D drugs, and are likely to incur annual drug costs above a certain threshold) are appropriately used to optimize therapeutic outcomes through improved medication use; is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries; may be furnished by a pharmacist or other qualified provider; and may distinguish between services in ambulatory and institutional settings. While services and interventions may vary across setting, the criteria for identifying targeted beneficiaries eligible for MTMP cannot.

those associated with submission of Medication Therapy Management Programs (MTMPs) and the plan benefit package detailing all the benefits offered under the plan. **Organizations must be prepared to meet the timelines specified in this section in order to be qualified for plan selection under demonstrations with effective enrollment dates of January 1, 2013.**

Although we expect that most demonstration proposals will be made public by early April, portions of the plan selection process will occur concurrently with the State demonstration approval process, which is described in more detail in Section IV of this guidance. As a result, interested organizations will need to notify CMS of their intent to apply through a non-binding NOIA (please refer to Section VI of this document for detailed instructions on that process), as well as develop and submit a formulary, MTMP, and plan benefit package, before all State demonstration proposals are approved and MOU negotiations are complete.

We recognize that interested plans will need additional detail beyond that provided in the calendar below. We expect to issue additional information about key operational timeframes as well as additional details on future plan selection criteria in partnership with respective State agencies pursuing demonstrations. This guidance will be issued in CMS sub-regulatory vehicles, including the CY 2013 Draft and Final Call Letters.

Key Date	Required Action
December 2011 –Summer 2012	States submit demonstration proposals that are evaluated against Standards and Conditions. States and CMS negotiate MOU for proposals that meet the Standards and Conditions. The MOU will outline specific programmatic design elements, technical parameters, and approval package for necessary Medicare and Medicaid authorities and payment/financial models.
January 2012	CMS and States provide information to interested plans on standards in key programmatic areas, as well as key operational dates and timelines to interested plans.
Early 2012	CMS to provide interested plans with training on demonstration requirements.
February 17, 2012	Release for public comment of the Contract Year (CY) 2013 Draft Call Letter.
March – July 2012	Health plans or other qualified entities are selected through a CMS-State joint selection process. Interested organizations submit required information regarding demonstration requirements, including licensure, network adequacy, and plan model of care. CMS and States review and select participating plans and begin contract negotiations with selected plans.

Key Date	Required Action
March 26, 2012	Release of HPMS Part D formulary submission module for CY 2013.* <i>*Applies to organizations offering demonstration and non-demonstration plans</i>
April 2, 2012	Release of CY 2013 Final Call Letter. Additional information on demonstration requirements and timelines provided to interested plans.
April 2, 2012	Latest date for Interested plans to submit their Notice of Intent to Apply (NOIA) to offer demonstration plans electronically to CMS through an online Web tool.
April 9, 2012	CMS User ID connectivity form submissions must be received <u>no later than this date</u> to ensure user access to the CMS Health Plan Management System (HPMS) ⁴ for purposes of submission of formulary and plan benefit package information.
April 23, 2012	Release of the CY 2013 Medication Therapy Management Program (MTMP) submission module in HPMS.* <i>*Applies to organizations offering demonstration and non-demonstration plans</i>
April 30, 2012	Part D formulary submissions due to CMS <u>for interested organizations that are submitting a new formulary (e.g., those that have not submitted a formulary for CY 2013 for non-demonstration plans).</u>
May 7, 2012	MTMP submission deadline. <i>*Applies to organizations offering demonstration and non-demonstration plans</i>
May 14, 2012	Part D formulary submissions due to CMS <u>for interested organizations that have already submitted a non-demonstration plan formulary for CY 2013 and intend to utilize that previously submitted formulary for their demonstration plans.</u> ⁵

⁴ HPMS is a system that supports contract management for Medicare health plans and prescription drug plans and supports data and information exchanges between CMS and health plans. Current and prospective Medicare health plans submit applications, information about provider networks, plan benefit packages, formularies, and other information via HPMS.

⁵ Note that organizations offering non-demonstration plans must submit their CY 2013 formularies by April 16, 2013.

Key Date	Required Action
June 4, 2012	<p>Submission of proposed plan benefit packages (including all Medicare and Medicaid benefits for demonstration plans) to CMS by interested organizations.*</p> <p><i>*Applies to organizations offering demonstration and non-demonstration plans</i></p>
June – July 2012	<p>CMS reviews submitted plan benefit packages.*</p> <p><i>*Applies to organizations offering demonstration and non-demonstration plans</i></p>
June 8, 2012	<p>Deadline for submitting Supplemental Formulary files, Free First Fill file, Partial Gap Coverage file, Excluded Drug File, Over-the-Counter Drug File, and Home Infusion File through HPMS.</p> <p><i>*Applies to organizations offering demonstration and non-demonstration plans</i></p>
July 30, 2012	<p>MTMP reviews completed.</p> <p><i>*Applies to organizations offering demonstration and non-demonstration plans</i></p>
July 30, 2012 (target date)	<p>Demonstration plan selection completed.</p>
Late July - September 2012	<p>CMS and State conduct readiness reviews for selected plans. CMS and States make final preparations for implementation, test all operational systems, and perform reviews to assure optimal preparation and adherence to contract requirements prior to implementation. CMS and States jointly confirm readiness requirements have been met.</p>
September 17, 2012 (target date)	<p>Roll-out of MA and Part D plan landscape documents, which include details (including high-level information about benefits and cost-sharing) about all available Medicare health and prescription drug plans for CY 2013.*</p> <p><i>*Applies to organizations offering demonstration and non-demonstration plans</i></p>
September 20, 2012 (target date)	<p>Three-way contracts between selected plans, States, and CMS must be finalized and signed <u>no later than this date</u>.</p>

Key Date	Required Action
Mid- to late September 2012	<p>CMS mails the CY 2013 <i>Medicare & You</i> handbook. The handbook includes high-level information – including basic cost-sharing and premium information – about available health plan options in a beneficiary’s specific geographic location.*</p> <p><i>*Applies to organizations offering demonstration and non-demonstration plans</i></p>
October 1, 2012	<p>For selected plans receiving passive enrollments of Medicare-Medicaid enrollees, notification of such enrollment and information about opt-out procedures must be sent to affected beneficiaries.</p>
October 1, 2012	<p>CY 2013 marketing activity begins.*</p> <p><i>*Applies to organizations offering demonstration and non-demonstration plans</i></p>
October 1, 2012	<p>Medicare Plan Finder on www.medicare.gov goes live for CY 2013.*</p> <p><i>*Applies to organizations offering demonstration and non-demonstration plans</i></p>
October 15 – December 7, 2012	<p>MA and Part D Annual Coordinated Election Period.*</p> <p><i>*Applies to organizations offering demonstration and non-demonstration plans</i></p>
January 1, 2013	<p>Enrollment effective date.*</p> <p><i>*Applies to organizations offering demonstration and non-demonstration plans</i></p>

C. Information for Organizations Offering Demonstration and Non-Demonstration Medicare Plans

Organizations that are currently offering or intend to offer non-demonstration MA or PDP products in 2013 will need to proceed with application and plan approval processes for those products separately from the process for plan selection under the demonstrations. We note that the NOIA deadline to offer non-demonstration MA plans and PDPs for contract year 2013 was in November 2011. Organizations that offer both demonstration and non-demonstration plans will be issued separate contract numbers for their proposed demonstration plans.

VI. Instructions for Submitting a Notice of Intent to Participate as a Demonstration Plan

CMS is pleased to announce the release of the Capitated Financial Alignment Demonstration Notice of Intent to Apply (NOIA) Web tool. Completion of this tool is required in order for interested organizations to obtain the necessary system access to meet the key deadlines articulated in the calendar in Section V of this guidance document. Since many of the State demonstration approval and demonstration plan selection processes will occur concurrently, any organization that is interested in working with a State to deliver the integrated benefits under these demonstrations must participate in this non-binding process and begin to prepare for the submission (either by itself or in partnership with a Pharmacy Benefit Manager, or PBM) of critical Part D requirements, including a formulary, Medication Therapy Management Program (MTMP), a pharmacy network, and a Part D benefit package). If an interested organization does not submit a NOIA by **April 2, 2012**, it will not be eligible to offer demonstration plans in 2013. We encourage interested organizations to submit a NOIA well before April 2, 2012 in order to ensure timely access to the Health Plan Management System (HPMS).

This NOIA process is separate from the process used for non-demonstration MA and PDP contracts. Organizations that are currently offering non-demonstration MA or PDP products will still need to submit a Capitated Financial Alignment Demonstration NOIA. Organizations with existing Medicare contracts will be issued a separate contract number specifically for their proposed demonstration plan(s).

The key dates related to this process are summarized below:

CY 2013 Application Activity	Date
Notice of Intent to Apply (NOIA) deadline* <i>*Organizations may submit a NOIA earlier, but must submit it <u>no later than</u> April 2, 2012.</i>	April 2, 2012
CMS User ID connectivity form submissions <u>must</u> be received by this date to ensure user access to HPMS.* <i>*Organizations that submit their NOIAs earlier should submit their CMS User ID connectivity forms as soon as possible following CMS' request to ensure access to HPMS as quickly as possible.</i>	April 9, 2012

A. Notice of Intent to Apply Requirements

CMS expects to provide interested organizations with additional instructions and key dates for submitting plan selection requirements, including licensure, network adequacy, and plan model of care information, in the CY 2013 Final Call Letter or other subregulatory vehicles no later than early April 2012. Given that some of the plan selection processes and requirements (e.g., submission of formularies, medication therapy management programs, and plan benefit packages) will be completed through the CMS Health Plan Management System (HPMS), demonstration applicants must have access

to HPMS. Timely completion of a NOIA and the CMS User ID connectivity form⁶ is necessary for ensuring HPMS access. Submitting a NOIA does not bind that organization to submit a formulary, MTMP, plan benefit package, or other required information. However, without a pending contract number and completed CMS User ID connectivity form, an interested organization will not be able to access the appropriate modules in HPMS to complete some of the requirements for participation in the demonstration. As a result, interested organizations that do not already have access to HPMS are encouraged to submit their NOIA as soon as possible in order to guarantee access in time to complete required modules by the dates detailed in Section V. Interested organizations that do not complete their NOIA submissions by **April 2, 2012** will not be eligible to offer demonstration plans in 2013.

B. Notice of Intent to Apply Submission Process

We encourage early submissions of Capitated Financial Alignment Demonstration NOIAs and will begin to accept NOIAs following the release of this guidance. The earlier interested organizations submit this information, the sooner they will have access to HPMS (note, for example, that the HPMS formulary submission module first becomes available March 26, 2012, but that an interested organization will not be able to access it until it has completed the NOIA process, meaning that it has both submitted the NOIA, as outlined in this section, and been assigned a CMS user ID, as specified below in section VI.C.) However, all NOIAs must be submitted by **5 p.m. Eastern Time on April 2, 2012**. CMS will not continue to process NOIAs for demonstration applicants after **April 2, 2012**. CMS will send confirmation emails to interested organizations once the Capitated Financial Alignment Demonstration NOIAs are processed and a contract number is assigned.

CMS will accept only NOIAs submitted electronically through its online Web tool. Organizations must use the following link to access and complete the NOIA Web tool:

<http://vovici.com/wsb.dll/s/11dc4g4ddb7>

A hard copy of the Web tool form is attached to this guidance as a reference for interested organizations (see Appendix 2). Appendix 2 identifies the questions an interested organization must complete to correctly request a pending contract number for an initial Capitated Financial Alignment Demonstration application. The assignment of contract numbers is done according to CMS rules. Interested organizations that already have existing Medicare Advantage or Prescription Drug Plan contracts will be assigned a separate contract number for the demonstration plan.

An interested organization must complete a separate NOIA for each State in which it intends to operate a demonstration plan. Please also note that P.O. boxes will not be accepted as a valid address for application purposes. Processing will be delayed for all NOIAs that contain a P.O. Box for the mailing address of the legal entity while CMS attempts to collect the street address for the legal entity.

C. CMS User IDs

All interested organizations submitting a NOIA will need CMS User IDs and passwords to access HPMS. After the NOIA is submitted, interested organizations will receive a confirmation email with the new

⁶ Note that only those organizations that are not currently Medicare contractors will need to complete a CMS User ID connectivity form.

contract ID and instructions for applying for a CMS User ID if they are not currently Medicare contractors.

Completed CMS User ID forms should be returned to CMS no later than **April 9, 2012**. We recommend that interested organizations use a traceable carrier to send the forms, and that they ensure they are submitting original forms with wet signatures (not copies). Organizations must identify where indicated all contract numbers that must be affiliated with the CMS User ID. Note that interested organizations will not be able to submit this form until CMS provides a pending contract number. Organizations must return the completed CMS User ID form to:

CMS
7500 Security Blvd
Mailstop C4-18-13
Baltimore, MD 21244
Attn: Lori Robinson

Existing Medicare contractor/HPMS users that would like to connect a pending contract number to current CMS User IDs must include the following information in an email to hpms_access@cms.hhs.gov:

1. User Name(s)
2. CMS User ID(s)
3. Current Contract Number(s)
4. Pending Contract Number(s)

Please refer technical questions about the Capitated Financial Alignment Demonstration NOIA process to Linda Anders at 410-786-0459 or Linda.Anders@cms.hhs.gov.

For questions related to HPMS user access, please send an email to hpms_access@cms.hhs.gov.

Any other questions about the demonstration timelines and requirements should be sent to CMS MMCOcapsmodel@cms.hhs.gov.

VII. Network Adequacy Determinations

As detailed in Appendix 1, CMS' preferred requirement standard for demonstrating network adequacy under the capitated financial alignment demonstration is to use Medicare standards for medical services and prescription drugs.^{7 8} For long-term care supports and services (LTSS), demonstration plans will use

⁷ Medicare Advantage requires that plans maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers. Also, plans must provide or arrange for necessary specialty care. The MA organization arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs. 42 CFR 422.112.

⁸ Part D plans must have a contracted pharmacy network that assures convenient access to network pharmacies, including retail, home infusion, long-term care, and I/T/U pharmacies. 42 CFR 423.120

State Medicaid network adequacy standards.⁹ For areas of overlap where services are covered under both Medicaid and Medicare (e.g., home health), the appropriate network adequacy standard will be determined via the CMS-State MOU negotiation and memorialized in the three-way contract with health plans, so long as such requirements result in a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

Demonstration plan applicants will work directly with States during the joint plan selection process to satisfy State-specific network adequacy requirements for LTSS and any Medicare/Medicaid overlapping services for which, under the MOU, the Medicaid standard has been agreed to by CMS and the State. In addition, interested organizations will work with CMS to submit the necessary documentation to be evaluated against Medicare network standards for Part D and medical services. Demonstration plan network adequacy will be subject to confirmation through readiness reviews.

Demonstration plans will be able to utilize an exceptions process in areas where Medicare's medical service network adequacy standards may not reflect the number of dual eligible beneficiaries. As part of the joint selection process for demonstration plans, we will establish a joint State/CMS exceptions review team to evaluate exceptions requests for portions of demonstration plan service areas where the Medicare medical service standard cannot be met or where an alternate standard has been negotiated in the MOU. The State/CMS exceptions review team will review all submitted exceptions requests and make determinations about the adequacy of plans' network in areas where exceptions have been requested.

We expect to provide more information in the Final Call Letter about timelines associated with submission and evaluation of network adequacy information.

⁹ Medicaid managed care contracts must require the plan give assurances to the State and provide supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care. Among other requirements, plans must maintain a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area. 42 CFR 438.207

Appendix 1: Comparison of Existing Managed Care Plan Requirements and Preferred Requirement Standards for Financial Alignment Demonstration Plans (as of 1.20.11)

The following chart summarizes Medicare and Medicaid requirements in these key programmatic areas and the pre-established parameter and/or preferred requirement standard in each area. Pre-established parameters are those demonstration parameters that have been determined and were announced in the MOU template that was released in the July 8, 2011 SMD letter. Preferred standards are CMS’ starting point for the framework to be utilized under the State demonstrations and will be discussed in more detail with States as part of their demonstration and MOU development and approval processes. The MOU will ultimately be the basis of each three-way contract.

Issue	Federal Medicaid Requirements	Medicare Requirements	Pre-Established Parameter and/or Preferred Requirement Standard
<p>1. Payment to Health Plans</p>	<p>States must pay rates that meet CMS actuarial soundness requirements. States may also establish additional requirements, e.g. risk adjustment, quality incentives, and risk corridors. States have flexibility in their rate-setting methodology; most set rates, but some do require plans to submit bids. 42 CFR 436.6 Plans may cover services above those required in the contract, but the cost of these may not be included in the payment rate. 42 CFR 438.6</p>	<p>Plans must submit Part C bid for monthly aggregate amount (Part C covered services and supplemental benefits) that meet CMS actuarial guidelines. Part C payments are linked to benchmarks connected to FFS experience and the plan’s quality rating (see “Prescription Drug” row for Part D payment). Plans must share Part C rebates (a portion of savings for bids below the benchmark) with beneficiaries via premium reduction or supplemental benefits. CMS risk adjusts the bid and rebate payments for each plan. Plans are fully at risk and are not subject to risk sharing. 42 CFR 422 Subparts F and G.</p>	<p>Pre-Established Parameter: Plans will be paid on a capitated basis for the full continuum of Medicaid and Medicare Part C benefits provided to Medicare-Medicaid enrollees. No Part C or D premiums will be charged to beneficiaries.</p> <p>Rates for participating plans will be developed based on baseline spending in both programs and anticipated savings that will result from integrated managed care (SMD MOU template sec. III.I). As designed, aggregate savings compared to baseline costs will be “shared” proportionally by both States and CMS. Rates will be subject to OACT review. [Please see #3 below for additional payment information on Part D benefit]</p>
<p>2. Plan Selection</p>	<p>There is no Federal requirement that States accept all qualified plans, which means that States may limit the number of plans that can participate (though if there is mandatory enrollment they must generally assure a choice of at least two managed care entities). They may identify when new plans may seek to participate (e.g., may choose how often procurement happens). 42 CFR 438.52</p>	<p>Medicare has an annual contracting process, in which MA plans that apply and meet specified requirements may participate. Medicare generally cannot limit the number of plans an MA organization may offer, but does require that plans of the same type (e.g., HMO, PPO, PFFS) submitted by a given MA organization have “meaningful differences,” as well as minimum enrollment levels to renew. 42 CFR 422 Subpart K</p>	<p>Pre-Established Parameter: Utilize joint plan selection process, either procurement or certification process (where approved) to select limited number of qualified plans. (SMD MOU template sec. III.2)</p> <p>Preferred Requirement Standard: The joint selection process will take into account previous performance in Medicare and Medicaid.</p>

<p>3. Prescription Drugs</p>	<p>For non-Medicare-Medicaid enrollees, States may provide prescription drug coverage through FFS or managed care. States may use utilization management tools such as prior authorization or formularies.</p> <p>There is no Federal financial participation for prescription drug coverage for Medicare-Medicaid enrollees who are eligible to enroll in a Medicare Part D plan (even if they are not actually enrolled).</p> <p>States may provide coverage of Part D excluded drugs for Medicare-Medicaid enrollees using State-only funds.</p>	<p>Plans are paid four types of Part D subsidies: a direct subsidy, a reinsurance subsidy and two subsidies to cover premium and cost-sharing expenses for low-income beneficiaries. Plans submit bids for the direct subsidy, which are risk adjusted and subject to risk sharing. The reinsurance and low-income cost-sharing subsidies are 100% cost reconciled. Details on the Part D benefit may be found in:</p> <p>Prescription Drug Benefit Manual: https://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp</p> <p>Part D Applications: https://www.cms.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp</p> <p>Part C Applications: http://www.cms.gov/MedicareAdvantageApps/</p> <p>Part D Regulations 42 CFR 423 Subparts F, G, and P: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=a2918a376335d69090f142a9da45e81f&rgn=div5&view=text&node=42:3.0.1.1.10&idno=42</p>	<p>Preferred Requirement Standard: Participating health plans will be paid according to the regular Part D payment rules, with the exception that the direct subsidy will be based not on a bid submitted by each plan, but on the standardized national Part D average bid amount. This national average bid amount will be risk adjusted according to the same rules that apply for all other Part D plans.</p> <p>Plans participating in the demonstration would be required to meet all other Medicare Part D requirements (e.g., benefits, network adequacy), and submit formularies and prescription drug event data. However, they would not be required to submit a bid. Beneficiaries in the demonstration would not be subject to any Part D premiums, but would continue to be subject to standard LIS copayment levels.</p> <p>Part D requirements can be located at the following links:</p> <p>Prescription Drug Benefit Manual: https://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage</p> <p>Part D Applications: https://www.cms.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp#TopOfPage</p> <p>Part D Regulations: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=a2918a376335d69090f142a9da45e81f&rgn=div5&view=text&node=42:3.0.1.1.10&idno=42</p>
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<p>4. Enrollment -- General</p>	<p>Permits voluntary or mandatory enrollment into health plans, with CMS approval. States that mandate enrollment into managed care entities must permit one chance to change plans within first 90 days of enrollment; an annual opportunity to change plans; and disenrollment for cause at any time (but these changes are usually limited to changing among plans rather than back to FFS). States vary in entities they permit to accept enrollment (for example, enrollment brokers). 42 CFR 438.56</p>	<p>Permits voluntary, beneficiary-initiated enrollment into MA and Part D plans, generally with lock-in through the end of the year thereafter, and with an annual coordinated election period each fall during which plans may be changed effective January 1. There are Special Election Periods that permit individuals to change plans outside that timeframe, including a continuous SEP that permits Medicare-Medicaid beneficiaries to change MA or PDP plans or disenroll back to Original Medicare at any time. Permits CMS to conduct passive enrollment into Part C and D plans in specific, limited circumstances (e.g., to prevent beneficiary harm or as a result of immediate plan termination), as provided under 42 CFR 422.60(g). Requires auto-enrollment of new Medicare-Medicaid enrollees into zero-premium Part D plans on a random basis (though they may disenroll at any time). 42 CFR 422 and 423 Subpart B</p>	<p>Pre-Established Parameter: For Medicare, States participating in the demonstration may request CMS approval for a passive enrollment process to enroll Medicare-Medicaid beneficiaries into participating health plans. Passive enrollment will require advance notice and an option upfront for beneficiary to opt out (or switch health plans) as well as an opportunity for the beneficiary to disenroll after enrollment is effective (SMD MOU template sec. III.C.2). Existing Medicaid authorities and protections will be maintained. This includes the option to submit waiver requests and/or plan amendments, requiring CMS review and prior-approval. Eligible population is full duals (SMD MOU template sec. III.C.1).</p> <p>Preferred Requirement Standard: All enrollments must ultimately be operationalized in CMS' systems to ensure that there is no duplication of coverage or payment.</p>
<p>5. Enrollment Effective Date</p>	<p>There are no federal requirements on when a contract year must start, so it varies by State. States with enrollee lock-in must offer an annual chance to change plans.</p>	<p>The contract year starts January 1. For individuals subject to lock-in, there is an "open enrollment" period October 15-December 7 in which they can change plans, for an effective date of January 1 of the following year.</p> <p>Medicare-Medicaid enrollees' Special Enrollment Period permits them to change up to monthly, with an effective date of the first of the following month.</p>	<p>Preferred Requirement Standard: For purposes of minimizing beneficiary disruption and confusion, ensure that passive enrollment process coincides with the underlying MA and Part C/D timeline such that beneficiary notice of demonstration options occurs prior to the annual coordinated election period (October 15 – December 7) in 2012.</p>

<p>6. Medical Loss Ratio (MLR)</p>	<p>There is no federal Medicaid requirement for MLR.</p>	<p>Beginning in 2014 contract year MA plans will be required to maintain an MLR of at least 85%.</p>	<p>Pre-Established Parameter: There will not be a minimum MLR requirement in the demonstration. However, participating plans will be required to report on costs to ensure transparency and facilitate evaluation, so we expect to have MLR information to determine what portion of premium participating health plans are spending on medical costs.</p>
<p>7. Solvency</p>	<p>Plans must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the entity's debts if the entity becomes insolvent. Several types of entities are not subject to this requirement, including Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, public entities, entities whose solvency are guaranteed by the State, Federally qualified Health Centers or Rural Health Centers receiving grants from HRSA (or entities controlled by these centers) or entities who had prepaid risk contracts with States prior to 1970.</p> <p>Except as noted above, entities must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity. 1903(m)(1)(A) and (B); 42 CFR 438.116</p>	<p>Defers to State licensure requirement (i.e., requires the MA plans to meet State solvency and licensure standards). Each MA organization must be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers one or more MA plans. If not commercially licensed, it must obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an MA organization. 42 CFR 422.400</p>	<p>Preferred Requirement Standard: Medicaid, as Medicare requirements already cede to State licensure and solvency requirements. However, in other areas related to the operation of an MA plan, federal law preempts state law (42 CFR 422.402)</p>

<p>8. Network adequacy</p>	<p>Medicaid managed care contracts require the plan to give assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care.</p> <p>Among other requirements, plans must maintain a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area. 42 CFR 438.207</p>	<p>Medicare Advantage requires that plans must maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.</p> <p>Also, plans must provide or arrange for necessary specialty care. The MA organization arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs. 42 CFR 422.112</p> <p>Exceptions to the Criteria CMS recognizes that in certain cases, an applicant's contracted network may not meet the provider network adequacy criteria. In such cases, the applicant may request an exception, from a pre-defined list created by CMS, for a specific provider/facility type in a specific county. These exceptions are detailed in the CMS Health Services Delivery Tables Exceptions Guidance. Plans must have a contracted pharmacy network that assures convenient access to network pharmacies, including retail, home infusion, long-term care, and I/T/U pharmacies. 42 CFR 423.120</p>	<p>Preferred Requirement Standard: Use State Medicaid standards for long term care networks and use Medicare standards for medical services and prescription drugs. Demonstration plans will be able to utilize an exceptions process in areas where Medicare network standards may not reflect the number of Medicare-Medicaid beneficiaries. Plans will be required to use Medicare network adequacy standards and review processes during plan selection process and network adequacy will be subject to confirmation through readiness reviews.</p> <p>For areas of overlap where services are covered under both Medicaid and Medicare, the appropriate network adequacy standard will be determined via MOU negotiation and memorialized in three-way contracts with health plans, so long as such requirements result in a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area. Note: Part D requirements will continue to be applied; see #3 for details.</p>
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9. Out of Network Reimbursement	<p>With the exception of emergency services, for which hospitals are required to accept the Medicaid state plan rate, Medicaid does not impose requirements on plans related to out-of-network payment levels, which sometimes results in plans being at risk for high payments, e.g. if imposed by highly specialized providers.</p>	<p>Medicare requires out of network coverage for urgent/emergent services. 42 CFR 422.113(b)(2). For those services, plans must pay non-contract providers (and those providers must accept payment) at Medicare FFS level. 42 CFR 422.214</p>	<p>Preferred Requirement Standard: FFS payment rate is required to be paid by plan and accepted by provider, as provided for in federal regulation and applicable State law and regulations.</p> <p>Note: Part D requirements will continue to be applied; see #3 for details.</p>
<p>Appeals:</p> <p>Pre-Established Parameter: the demonstration will include a uniform appeals process. We recognize that in some States this may require regulatory changes or legislative approval, which could take some time; all contracts will require changes to be undertaken as expeditiously as possible. We also recognize that there are other circumstances (e.g. court orders) that may make certain aspects of a uniform appeals process a challenge.</p> <p>Note: Unless indicated otherwise, Part D appeal standards will remain unchanged.</p>			
10. Appeals – Timeframes for filing an appeal related to benefits	<p>Appeals may be filed with the plan anywhere between 20 and 90 days (varies by States). States are permitted to give enrollees direct access to State fair hearing process rather than exhausting plan appeals. 42 CFR 438.408.</p>	<p>Part C: Appeals must be filed within 60 days. 42 CFR 422.582 (reconsideration) 42 CFR 422.592 (IRE), 42 CFR 422.602 (ALJ).</p>	<p>Preferred Requirement Standard: Medicare – 60 days to file an appeal. If it is not possible for State to change Medicaid time frames currently in State regulation by 2013, use Medicare standard unless State Medicaid standard is more generous (i.e. allowable timeframe is greater than 60 days).</p>
11. Appeals – Access to State level or external review	<p>All States must provide access to a State Fair Hearing, either directly or (if the State requires exhaustion of the health plan level of appeal) after an initial appeal to the health plan. 42 CFR 431.205 and §438.408; and section 1902(a)(3) of the Act. Some States provide access to Ombudsman or Independent Review Entities for those enrolled in managed care.</p>	<p>Part C and D: Medicare allows beneficiaries in private health plans to access Independent Review Entities, but only after the filing of an initial appeal to a plan. 42 CFR 422.578, 422.592 for Part C; 42 CFR 423,580, 423, 600 for Part D.</p>	<p>Preferred Requirement Standard: Medicare – internal appeals should ideally go through the plan first, and then external appeals should go through the Medicare qualified independent contractor. However, some States enable beneficiaries to bypass plan internal appeal processes and seek out external appeals immediately. Absent regulatory change– the MMCO will not have the authority to prevent beneficiaries from seeking out external appeals through these channels prior to internal appeals processes in such States. Accordingly, States will be encouraged to provide—via contract, regulation or both—for initial appeals to be made via the plan first.</p>

<p>12. Appeals – Continuation of benefits pending appeal</p>	<p>Medicaid benefits generally continue and are paid for pending a timely appeal (FFP is available for these costs), when the appeal is requested within a certain timeframe. Note: this standard applies to reduction or termination of items or services. States also may reinstate benefits if requested within 10 days of the date of action (States vary). 42 CFR 431.231. Section 1902(a)(3) of the Act; 42 CFR 431.205; §438.420 (managed care). The State may seek recovery against the beneficiary if he or she loses the appeal.</p>	<p>Other than terminations of inpatient hospital care or other services by a “provider of services” (such as a nursing home or home health agency, which are covered regardless of the outcome of the initial level of appeal), benefits do not continue during the pendency of a Medicare appeal involving reduction or termination of items or services.</p>	<p>Preferred Requirement Standard: Hybrid – during internal plan review, benefits should be continued (per Medicaid standard), however once appeals reach external Medicare level, benefits not continued (per Medicare standard). Medicaid-only benefits would continue, per current standards. Note: only benefits that are initially provided and subsequently reduced or terminated may continue pending an initial appeal.</p>
<p>13. Appeals – Document notifying beneficiaries of appeal rights</p>	<p>Various documents may be used to notify beneficiaries of their appeal rights depending upon the State. Regulations require that information about appeals be included at the time of application, with a notice of adverse action on a claim, at the time of transfer or discharge from a SNF. 42 CFR 431.206. Also there are requirements of providing notice to beneficiaries enrolled in managed care organizations during terminations, suspensions, reductions in service, denial of payment, among others. 42 CFR 438.404.</p>	<p>Medicare Part C: Various denial notices are sent for specific coverage denials, and the Evidence of Coverage contains specific enrollee guidance regarding appeal rights. Medicare Part D: Various denial notices are sent for specific coverage denials, and the Evidence of Coverage contains specific enrollee guidance regarding appeal rights.</p>	<p>Preferred Requirement Standard: Hybrid – one document that explains integrated appeals process.</p>
<p>14. Appeals – Timeframes for resolution of an appeal related to benefits</p>	<p>Standard appeals must generally be handled within 45 days, with extensions available in certain circumstances. Expedited appeals are to be handled within 3 working days, with extensions up to 14 calendar days in certain circumstances. 42 CFR 438.402, and §438.408.</p>	<p>Part C and D: Standard plan reconsiderations must be resolved within 7 days (Part D) or 30 days (Part C). Expedited reviews are to be conducted within 72 hours.</p>	<p>Preferred Requirement Standard: Medicare -- 30 days for standard appeals per the Medicare Part C standard, and 72 hours for expedited appeals per the Medicare standard.</p>

<p>15. Benefits/ Medical Necessity</p>	<p>Each State must ensure that all services covered under the State plan and are included in the plan contract are available and accessible to enrollees to the extent they are in FFS, and using a medical necessity definition that is no more restrictive than that used in the State's Medicaid program. 42 CFR 438.210(a)(4)</p>	<p>Medicare covers medically necessary Part A and B services, i.e., those that are necessary for the diagnosis or treatment of illness or injury or to improve the functioning of malformed body members. If there is a question about new services, CMS will issue a national coverage determination or local decisions will be articulated in Local Medical Review policies. MA plans may also offer supplemental benefits beyond those required under Medicare Parts A and B (e.g., dental care and vision benefits). Section 1862(a)(1)(A) of the Act. 42 CFR §422.101 and §422.102.</p>	<p>Pre-Established Parameter: CMS and State may choose to allow for greater flexibility in supplemental benefits than currently permitted under either program, provided that they are in the blended rate. (SMD MOU template sec III.D.1).</p> <p>Preferred Requirement Standard: Medicare standards for acute services and prescription drugs and Medicaid standards for long term care services and supports, where there is overlap coverage will be determined by contract.</p>
<p>16. Marketing/ Beneficiary Information</p>	<p>Medicaid defines marketing as communication to non-enrollees with intent to persuade them to enroll. Cold calls are prohibited. Marketing materials must be prior approved by State. States may prohibit plan marketing altogether. 42 CFR 438.104 Plans must also provide specified information to potential enrollees as well as to enrollees (these are not considered "marketing."). The State must specify language and readability thresholds. 42 CFR 438.10</p>	<p>Medicare defines marketing as communications to potential enrollees as well as enrollees (certain ad hoc communications to enrollees are exempted). MA organizations and Part D sponsors must meet certain minimum requirements with respect to disclosure of plan information and marketing limitations. CMS must prior approve certain marketing materials (not that there is a "file and use" process for plans that does not require prospective CMS review of certain marketing materials). CMS requires plans to use certain standardized model marketing materials and notices. Plans must translate certain materials if a language is spoken by 5% of enrollees at plan benefit package level. 42 CFR 422.111, §423.128, Subpart V of Part 422, Subpart V of Part 423.</p> <p>As specified in subregulatory guidance, there are a broad range of standardized and model documents under the MA and Part D programs, some of which apply generally to all MA plans, but some of which were designed specifically for SNPs.</p>	<p>Pre-Established Parameter: Flexibilities include unified marketing requirements/review process. Enrollee materials shall be integrated to the extent possible, and must be accessible and understandable to beneficiaries, including those with disabilities and limited English proficiency. CMS and State will prior approve all outreach and marketing materials, subject to single set of rules (SMD MOU template sec. I; III.C.4; III.E.2). Note: Part D requirements will continue to be applied; see #3 for details.</p> <p>Preferred Requirement Standard: A flexible approach to both minimum marketing requirements and review processes. Consistent set of required beneficiary information. For readability and translation standards, defer to whichever standard is more beneficiary-friendly.</p>

<p>17. Quality -- Reporting measures</p>	<p>Federal Medicaid regulations require States to have plans report performance measures (with State specifying the measures). States may require measures to be reported on State contracting cycles (which may differ from Federal cycles). 42 CFR 438.240(d)</p>	<p>MA plans must “measure performance under the plan, using the measurement tools required by CMS, and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.” 42 CFR 422.152</p> <p>Reporting requirements also detailed here:</p> <p>http://www.cms.gov/HealthPlansGenInfo/Downloads/PartCTechSpecs_Oct11.pdf</p> <p>http://www.cms.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp</p> <p>SNPs have additional requirements to measure performance under the plan, using the measurement tools required by CMS, and report performance to CMS. They must also provide outcome measures that are reported as part of materials beneficiaries use to select plans. 42 CFR 422.152(b)(3).</p> <p>SNP HEDIS measure requirements, as of 2009, are available here:</p> <p>http://www.cms.gov/SpecialNeedsPlans/Downloads/2009_SNP_HEDIS_Reporting_Regts.pdf</p> <p>CMS, together with the NCQA, has also developed six structure and process measures for SNPs.</p>	<p>Pre-Established Parameter: CMS and State shall determine applicable standards, and jointly conduct a single comprehensive quality management process and consolidated reporting process.(SMD MOU template sec. III.G.3, III.H.1 -3)</p> <p>Preferred Requirement Standard: Require strong, consistent quality oversight and monitoring requirements. Quality requirements will be integrated but will include some measures currently used by Medicaid and Medicare. The core set of measures will allow quality to be evaluated and compared with other plans in the model as well as other non-model plans.</p> <p>Prescription drug quality reporting measures will be at least consistent with Medicare Part D requirements.</p>
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<p>18. Quality – Performance Improvement</p>	<p>Performance Improvement Plan: The State must require, through its contracts, that each managed care entity have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees. 42 CFR 438.240</p> <p>Role of External Reviewer: States must contract with an External Quality Review Organization for each contract. 42 CFR 438.350</p>	<p>Performance Improvement Plan: Medicare requires the development of an ongoing quality improvement program, including submission of chronic care improvement programs and quality improvement projects for each MA plan. 42 CFR 422.152</p> <p>Role of External Reviewer: CMS is permitted to use quality improvement organization data for various functions. 42 CFR 422.153</p>	<p>Pre-Established Parameter: CMS and State shall determine applicable standards, and jointly conduct a single comprehensive quality management process. (SMD MOU template sec. III.H.1 -3)</p> <p>Preferred Requirement Standard: Advance an integrated quality/performance improvement program for plans, and have a single entity receive and review this integrated report and other quality measures. This reduces administrative burden on plans to have integrated reporting requirements; further, in some States the same contractor fulfills the EQRO and QIO function.</p>
<p>19. Quality Incentives</p>	<p>States may provide for incentive payments if plans meet certain targets (including quality). 42 CFR 438.6</p>	<p>MA has quality bonuses based on star ratings. 42 CFR 422.260</p>	<p>Pre-Established Parameter: Participating plans will not be eligible for star bonuses. Plans will be subject to an increasing quality withhold (1, 2, 3 percent in years 1, 2, and 3 of the demonstration). Plans will be able to earn back the capitation revenue if they meet quality objectives.</p>
<p>20. Model of Care</p>	<p>Medicaid requirements do not specifically reference “model of care,” but do require State contracts with plans include primary care source, coordination of other services, and for special needs individuals, an assessment and treatment plan. 42 CFR 438.208</p>	<p>Under the MA program, a Special Needs Plan is required to have a model of care, in addition to standard MA requirements for care coordination. In addition, all plans that offer Part D are required to have a medication therapy management program. Starting in 2012, all SNPs’ models of care must be approved by NCQA based on CMS standards. 42 CFR §§ 422.4(a)(iv), 422.101(f), and 422.152(g).</p>	<p>Preferred Requirement Standard: Unified model of care requirements for participating health plans.</p>

<p>21. Oversight Monitoring Auditing Program Integrity</p>	<p>CMS Medicaid regulations require generally a plan must comply with the applicable certification, program integrity and prohibited affiliation rules and requirements. 42 CFR 438.600 et. seq. CMS Medicaid regulations require State agencies to monitor plan operations, including, at a minimum:</p> <ul style="list-style-type: none"> - Recipient enrollment and disenrollment. - Grievances and appeals - Violations subject to intermediate sanctions - Violations of conditions for Federal payment. <p>42 CFR 438.66</p>	<p>Medicare contracts with plan specify inspection and auditing rights.</p>	<p>Pre-Established Parameter: CMS-State contract management team to ensure access, quality, program integrity, and financial solvency, including reviewing/acting on data/reports; conducting studies/corrective action.</p> <p>Preferred Requirement Standard: Coordinated oversight, as negotiated and determined in MOU or contract. States may conduct auditing function and monitor plans for compliance with demonstration standards if they can establish to CMS’ satisfaction that its standards meet or exceed Medicare’s.</p> <p>Note: Part D requirements will continue to be applied; see #3 for details. States will be informed of results found and actions taken.</p>
<p>22. Encounter Data: Collection and Validation</p>	<p>States must collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees, through an encounter data system or other methods as may be specified by the State. 42 CFR 438.242 EQRO entities may perform encounter data validation functions for the State.</p>	<p>CMS has authority to collect information from MA plans to justify each item and service provided by plan, and has imposed specific encounter data reporting requirements on plans starting with contract year 2012. 42 CFR 422.310.</p>	<p>Preferred Requirement Standard: Uniform encounter reporting. Note: Part D requirements for reporting Prescription Drug Event (PDE) data will continue to be applied; see #3 for details.</p>
<p>23. Credentialing</p>	<p>Each State must establish a uniform credentialing and re-credentialing policy that each plan must follow. These must include anti-discrimination provisions for providers that serve high-risk populations or specialize in conditions that require costly treatment. 42 CFR 438.214</p>	<p>MA organizations must have written policies and procedures for the selection and evaluation of providers that conform to Medicare requirements. “Providers of Services” must have a Medicare provider agreement in place.</p>	<p>Preferred Requirement Standard: Medicaid standards apply, i.e., plans can use Medicaid standards for certifying that participating providers are credentialed.</p>

Appendix 2: Notice of Intent to Apply for Capitated Financial Alignment Demonstration Contracts

To ensure clear and timely communication with CMS, all organizations interested in offering Capitated Financial Alignment Demonstration plans starting in CY 2013 must notify CMS of their intent to apply to offer such a plan by completing this Notice of Intent to Apply (NOIA) form online at:

<http://vovici.com/wsb.dll/s/11dc4g4ddb7>

1) Applicant Organization’s Legal Entity Information.

NOTE: Organizations must provide street addresses for the location of the Legal Entity. PO Boxes are not acceptable and CMS will only process NOIAs with a street address.

Legal Entity Name: _____
Street Address 1: _____
Street Address 2: _____
City, State ZIP: _____

2) Select Parent Organization* from the pull down list provided in Web tool. [Note that if there is no applicable parent organization in the pull down list provided in the Web tool, you must select “Other”]

* CMS considers a parent organization to be the legal entity that owns a controlling interest in a contracting organization. The parent organization is the “ultimate” parent, or the top entity in a hierarchy (which may include other parent organizations) of subsidiary organizations which is not itself a subsidiary of any corporation.

3) The legal entity identified above has Contract Year 2012 Medicare Part C or D contracts (with or without Employer Group Waiver Plans (EGWPs) or Special Needs Plans (SNPs)) with CMS as follows (check all that apply):

- MA-PD HMO/HMOPOS
- MA-PD Local PPO (LPPO)
- MA-PD Regional PPO (RPPO)
- MA-PD PSO
- MA-PD PFFS (with Part D)
- Medicare Advantage Only – PFFS
- Medicare Advantage Only – MSA
- 1876 Cost Plan with Part D
- 1876 Cost Plan no Part D
- PDP
- Employer/Union Direct PFFS with Part D
- Employer/Union Direct PFFS no Part D
- Employer Direct MA-PD LPPO
- Employer Direct PDP
- Not Applicable - Legal Entity does not hold a 2012 Medicare Part C or Part D contract with CMS

- 4) **The legal entity identified above has Contract Year 2012 Medicare Part C or D contracts that include Dual Eligible Special Needs Plans (D-SNPs):**
- Yes
 - No
- 5) **[Complete only you selected “yes” for Question 4] Approximately how many full dual eligible individuals do all of the SNP products offered by the legal entity identified above currently serve?**
- [Enter total number of covered lives]
- 6) **The parent organization identified above has Contract Year 2012 Medicare Part C or D contracts that include Dual Eligible Special Needs Plans (D-SNPs):**
- Yes
 - No
- 7) **[Complete only you selected “yes” for Question 6] Approximately how many full dual eligible individuals do all of the SNP products offered by the parent organization identified above currently serve?**
- [Enter total number of covered lives]
- 8) **Does the legal entity identified above offer Medicaid managed care products in any State?**
- Yes
 - No
- 9) **[Complete only if you selected “yes” for Question 8] Approximately how many full dual eligible individuals do the Medicaid managed care products operated by the legal entity identified above currently serve in all States in which that legal entity operates?**
- [Enter total number of covered lives]
- 10) **Does the parent organization identified above offer Medicaid managed care products in any State?**
- Yes
 - No
- 11) **[Complete only if you selected “yes” for Question 10] Approximately how many full dual eligible individuals do the Medicaid managed care products operated by the parent organization identified above currently serve in all States in which that parent organization operates?**
- [Enter total number of covered lives]

12) Capitated Financial Alignment Demonstration Plan Contact Information.

Salutation: _____
 First Name: _____
 Last Name: _____
 Title: _____
 Street Address 1: _____

Street Address 2: _____
City, State ZIP: _____
Legal Entity Name: _____
Street Address 1: _____
Street Address 2: _____
City, State ZIP: _____

13) Select the type of NEW contract product type for which your organization will apply (refer to section 30 of Chapter 1 of the Medicare Managed Care Manual, <https://www.cms.gov/manuals/downloads/mc86c01.pdf>, for definitions of the product types below). Check ONLY one; interested organizations must submit separate Notices of Intent to Apply for each demonstration contract product type. Note that legal entities with 2012 contracts with CMS will be issued a new contract ID for their demonstration plans.

- Medicare Advantage-Prescription Drug Plan Health Maintenance Organization (MA-PD HMO) / Medicare Advantage-Prescription Drug Plan Health Maintenance Organization Point-of-Service (MA-PD HMOPOS)
- MA-PD Local Preferred Provider Organization (MA-PD LPPO)
- MA-PD Regional Preferred Provider Organization (MA-PD RPPO)

14) Select the State for which your organization intends to submit an application. Check ONLY one; interested organizations must submit separate Notices of Intent to Apply for each State for which they intend to submit an application.

- Arizona
- California
- Delaware
- Florida
- Hawaii
- Idaho
- Illinois
- Indiana
- Kansas
- Kentucky
- Massachusetts
- Michigan
- Minnesota
- New Mexico
- New York
- Ohio
- Oregon
- Pennsylvania
- Rhode Island
- South Carolina
- Tennessee
- Texas
- Vermont
- Virginia

- Washington
- Wisconsin

15) Does your organization intend to use a Pharmacy Benefit Manager (PBM) with experience administering the Part D benefit?

- Yes
- No
- Undecided

16) [Complete only if you selected “yes” for Question 12] What is the name of the PBM you intend to use to administer your Part D benefit under your demonstration plan?

- [Enter name of PBM]

17) Does your organization intend to utilize a CY 2013 Part D formulary submitted for any other non-demonstration Medicare Part C or Part D contract?

- Yes
- No

NOTE: Once you click "Submit 'Notice of Intent to Apply' Responses Now" you will not be able to return to this specific Capitated Financial Alignment Demonstration Notice of Intent to Apply.

If your organization has additional NOIAs (for different States), you must complete one NOIA for each additional State.

If you need to submit notices for additional Capitated Financial Alignment Demonstration applications, after clicking the "Submit Notice of Intent to Apply" button, return to the NOIA online form by following the link in the memo announcing the NOIA, or copy and paste this link in your browser:

<http://vovici.com/wsb.dll/s/11dc4g4ddb7>