Final Contract Year (CY) 2019 Marketing Guidance for New York's Fully-Integrated Duals Advantage (FIDA) Medicare-Medicaid Plans

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Introduction

All Medicare Advantage-Prescription Drug (MA-PD) plan sponsor requirements in the Contract Year (CY) 2019 Medicare Communications and Marketing Guidelines (MCMG), posted at http://www.cms.gov/Medicare/Health-

Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html, apply to the Medicare-Medicaid Plans (MMPs) participating in the New York capitated financial alignment model demonstration – also referred to as Fully-Integrated Duals Advantage (FIDA) Plans – except as noted or modified in this guidance document. Plans are also required to follow all applicable New York State and federal regulations regarding marketing, including 18 CRR-NY 360-10.9 and 42 CFR 438.104.¹ For purposes of this document, we refer to MMPs as FIDA Plans, though we note that CMS uses the term MMP to refer to all plans in all states participating in capitated financial alignment model demonstrations. We also clarify that FIDA Plans may not distribute any marketing materials that require State approval without first obtaining State approval.

This guidance document provides information only about those sections of the MCMG that are not applicable or that are different for FIDA Plans in New York; therefore, this guidance document should be considered an addendum to the CY 2019 MCMG. In addition, this guidance document further clarifies marketing rules specific to New York State Medicaid requirements, which apply to the FIDA demonstration. This FIDA Plan guidance is applicable to all marketing done for CY 2019 benefits.

Use of Independent Agents and Brokers

We clarify that all requirements applicable to independent agents/brokers throughout the MCMG are inapplicable to FIDA Plans in New York because the use of independent agents/brokers is not permitted, and all FIDA Plan enrollment transactions must be processed by New York's enrollment broker.

Compliance with Section 1557 of the Affordable Care Act of 2010

FIDA Plans are subject to the disclosure requirements under Section 1557 of the Affordable Care Act. For more information, FIDA Plans should refer to https://www.hhs.gov/civil-rights/for-individuals/section-1557/.

Annual Marketing Plan

FIDA Plans are required to submit an annual marketing plan to the State for review and approval. More detail about this requirement is provided in section 10 of this document.

Formulary and Formulary Change Notice Requirements

FIDA Plans should refer to the November 1, 2018, HPMS guidance memorandum, "Part D Communication Materials," for guidance on formulary and formulary change notice requirements. As noted in that memorandum, additional updates to reflect changes related to 42 CFR 423.120(b)(5), regarding notice of mid-year formulary changes and changes to the definition of an approved month's supply, will be incorporated into the Medicare Prescription

¹ Note that any requirements for Special Needs Plans (SNPs), Private Fee-for-Service (PFFS) plans, Preferred Provider Organizations (PPOs), and Section 1876 Cost-Based Plans (cost plans) in the MCMG do not apply unless specifically noted in this guidance.

Drug Benefit Manual in a future release. In addition, we note that FIDA Plans are required to adhere to all new regulatory provisions and requirements.

The requirements of the November 1, 2018, HPMS guidance memorandum apply with the following modifications:

- Formulary change notices must be sent for any negative formulary change (as described in section 30.3.3, "Midyear Formulary Changes," and section 30.3.4, "Provision of Notice Regarding Formulary Changes," of Chapter 6 of the Prescription Drug Benefit Manual), regardless of whether or not the negative formulary change applies to an item covered under Medicare or Medicaid, or as an additional drug benefit under the plan.
- Formulary change notices applicable to all formulary changes (not just Part D drug changes) must be maintained on FIDA Plan websites.

Following are the New York FIDA Plan-specific modifications to the MCMG for CY 2019.

Section 10 - Introduction

FIDA Plans must submit a plan of FIDA Plan marketing activities to the State that sets forth the terms and conditions and proposed activities of the FIDA Plan dedicated staff during the contract period. The following must be included in the marketing plan:

- A description of materials and formats to be used;
- Distribution methods;
- Primary types of marketing locations (such as, but not limited to, senior centers, nursing facilities, health fairs, etc.); and
- A listing of the kinds of community service events the FIDA Plan anticipates sponsoring and/or participating in during which it will provide information and/or distribute FIDA Plan marketing materials.

An approved annual marketing plan must be on file with the State for its contracted service area prior to the FIDA Plan engaging in the FIDA Plan-specific marketing activities. The marketing plan may be submitted by September 30, 2018, or following the issuance of this guidance.

The marketing plan must include: (1) stated marketing goals and strategies; (2) a description of marketing activities, and the training, development and responsibilities of dedicated marketing staff; (3) a staffing plan, including personnel qualifications, training content and compensation methodology and levels; (4) a description of the FIDA Plan's monitoring activities to ensure compliance with this section; and (5) identification of the primary marketing locations at which marketing will be conducted. The FIDA Plan must describe how it will meet the informational needs related to marketing for the physical and cultural diversity of its potential membership. This includes, but is not limited to, a description of the FIDA Plan's other-than-English language provisions; interpreter services; and alternate communication mechanisms, including sign language, braille, audio tapes, and/or use of Telecommunications Devices for the Deaf (TDD) services. The FIDA Plan must describe measures for monitoring and enforcing compliance with these guidelines by its marketing representatives, including the prohibition of door-to-door

solicitation and unsolicited telephonic or electronic contact; a description of the development of pre-enrollee mailing lists that maintains client confidentiality and honors the client's express request for direct contact by the FIDA Plan; and a description of the training, compensation and supervision of its FIDA Plan dedicated marketing representatives.

We also note that FIDA Plans are still required to submit marketing events in HPMS. We also note that providers may not provide mailing lists of their patients to FIDA Plans. FIDA Plans may also not require providers to distribute Plan-prepared communications to their patients.

Section 20 - Communications and Marketing Definitions

MMPs are subject to marketing and beneficiary communications applicable to Medicare Advantage plans in 42 CFR 422 and 423, as well as those applicable to Medicaid managed care organizations in 42 CFR 438. CMS has developed a joint review process for MMP beneficiary materials under each Financial Alignment Initiative capitated model demonstration that combines State and CMS review requirements and parameters. Given these differences, CMS will continue to consider all CY 2019 MMP materials to be marketing materials as defined prior to the implementation of CMS-4182-F.² As a result, this section of the MCMG and its subsections do not apply to MMPs. We provide additional detail about materials subject to HPMS submission in the guidance related to section 90.1.1 of the MCMG in this document. In addition, for any other references to communications throughout the MCMG, the previous definition of marketing materials will apply.

Section 30.2 - Standardization of Plan Name Type

As is the case for other Medicare health plans, FIDA Plans are required to include the plan type in each plan's name using standard terminology consistent with the guidance provided in this section. CMS created the standardized plan type label "Medicare-Medicaid Plan" to refer generically to all plans participating in a capitated financial alignment model demonstration. FIDA Plans must use the "Medicare-Medicaid Plan" plan type terminology following their plan name at least once on the front page or beginning of each marketing piece, excluding envelopes, consistent with the requirements of section 30.2 of the MCMG. In addition, New York requires each plan to use the term "Fully-Integrated Duals Advantage" (FIDA) Plan to refer to any FIDA Plan operating in New York. Thus, we clarify that FIDA Plans must only use the CMS standardized plan type "Medicare-Medicaid Plan" following their plan name once in their materials but can then use the FIDA Plan terminology thereafter.

In addition, the State also expects FIDA Plans to use the term FIDA in their plan name, as entered in HPMS and included in their marketing materials. For example, a FIDA Plan in New York would use "Acme Duals FIDA Plan" as its plan marketing name in all Participant materials.

In addition, we clarify that FIDA Plans in New York that offer Medicare Advantage products, including SNPs, in the same service area as their FIDA Plans, may not use the same plan marketing name for both those products, so as to prevent Participant confusion. Thus, for example, an organization offering both a SNP and a FIDA Plan in the same service area could

² "Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE program," which may be found in the Federal Register published April 16, 2018 (see https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare).

not use the same name – e.g., Acme Duals Care (HMO SNP) – for its SNP product as for its FIDA Plan product – e.g., Acme Duals Care FIDA Plan (Medicare-Medicaid Plan).

Section 30.3 - Non-English Speaking Population

The standard articulated in this section for translation of marketing materials into non-English languages will be superseded to the extent that New York's standard for translation of marketing materials is more stringent. The New York translation standard – which requires translation of materials into a language that is the primary language of at least five (5) percent of the FIDA Plan's enrolled population or fifty (50) Participants, whichever is less – exceeds the Medicare standard for translation in New York FIDA Plan service areas. Guidance on the translation requirements for all plans, including FIDA Plans, is released via HPMS annually each fall. Required languages for translation for the MMPs are also updated annually, as needed, in the HPMS Marketing Module.

At a minimum, for CY 2019, it is our expectation that the FIDA Plans will continue to meet the Medicare standard for translation of required marketing materials into Spanish in all service areas. CMS and the State have designated materials that are vital and, therefore, must be translated into the non-English languages specified in this section.³ This information is located in section 100.4 of this document.

In addition, FIDA Plans must translate ad hoc Participant communication materials regarding payments and reimbursements in accordance with the standard described above. We note that ad hoc Participant communication materials are not considered marketing materials and are not submitted in HPMS for marketing review.

FIDA Plans must have a process to simply describe how they will request a Participant's preferred language and/or format for receiving the materials identified in this section and will keep the information as a standing request for future mailings and communications. FIDA Plans must also describe how a Participant can change a standing request for preferred language and/or format. Standing requests pertain to alternate formats and all non-English languages identified in this section and in the HPMS Marketing Module.

For additional information regarding notice and tagline requirements, please refer to Appendix A and Appendix B to Part 92 of Section 1557 of the Patient Protection and Affordable Care Act.

Section 40.2 - Marketing Through Unsolicited Contacts

Section 40.2 of the MCMG provides examples of unsolicited direct contact with current and prospective Participants. We reiterate that marketing via conventional mail and other print media (e.g., advertisements, direct mail) is not considered unsolicited contact and is, therefore, permissible. We also clarify that, both here and in section 40.3 of this guidance, marketing of FIDA Plans to current Participants (including those enrolled in other product lines such as its

³ CMS makes available Spanish translations of the New York FIDA Plan Summary of Benefits (SB), formulary (List of Covered Drugs), Provider and Pharmacy Network Directory, and ANOC/EOC (Participant Handbook). These are posted at <a href="https://www.cms.gov/Medicare-Medicaid-Coordination-Medicare-and-Medicaid-Coordination-Medicare-Medicaid-Coordination-Medicare-Medicaid-Coordination-Medicare-Medicaid-Coordination-Medicare-Medicaid-Medicare-Medicaid-Coordination-Medicare-Medicaid-Medicare-Medicaid-Medicare-Medicaid-Coordination-Medicare-Medicaid-Medicare-Medicaid-Coordination-Medicare-Medicaid-Medicare-Medicaid-Coordination-Medicare-Medicaid-Medicare-Medicaid-Medicare-Medicaid-Medicare-Medicaid-Medicare-Medicaid-Medicare-Medicaid-Medicare-Medicaid-Medicare-Medicaid

Medicaid managed care product) is not considered unsolicited direct contact and is, therefore, permissible.

We clarify that, under the MCMG, FIDA Plans are already permitted to send direct mail about the FIDA Plan to Participants who have opted out, regardless of whether they remain members of other non-FIDA products once they opt out of the FIDA Plan.

Section 40.3 - Marketing Through Telephonic Contact

The requirements of section 40.3 of the MCMG apply with the following clarifications and modifications:

- Consistent with section 40.3 of the MCMG, calls made by FIDA Plans to current Participants (including those enrolled in other product lines) are not considered unsolicited direct contact and are, therefore, permissible. Organizations offering FIDA Plans may call current non-FIDA Plan (e.g., managed long term care plan, Medicare Advantage plan) Participants, including individuals who have previously opted out of enrollment into a FIDA Plan, to promote the FIDA Plan.
- Plans may use reasonable efforts to contact current non-FIDA Plan Participants who are eligible for FIDA enrollment to provide information about their FIDA products. Callers with questions about other Medicare program options should be warm transferred to 1-800-MEDICARE or to the State Health Insurance Assistance Program (e.g., Health Insurance Information, Counseling, and Assistance, or HICAP) for information and assistance.

Section 40.4 - Nominal Gifts

Under the FIDA demonstration, FIDA Plans may not offer financial or other incentives of any kind to induce potential FIDA Plan Participants to enroll with the FIDA Plan or to refer a friend, neighbor, or other person to enroll with the plan. This includes nominal gifts provided at FIDA Plan-targeted events. However, nominal gifts may be offered to potential FIDA Plan Participants. Nominal gifts must be offered consistent with the guidance in section 40.4 of the MCMG.

Section 40.6 - Marketing Star Ratings

Because MMCO is in the process of developing a Star Ratings system for MMP performance, FIDA Plans will not be subject to the Star Ratings requirements in the MCMG. Therefore, this section does not apply to FIDA Plans.

Section 40.6.1 - Marketing Plans/Part D Sponsors with an Overall 5-Star Rating

Because MMCO is in the process of developing a Star Ratings system for MMP performance, FIDA Plans will not be subject to the Star Ratings requirements in the MCMG. Therefore, this section does not apply to FIDA Plans.

Section 40.8 - Marketing of Rewards and Incentives Programs

FIDA Plans may market rewards and incentives to current FIDA Plan Participants, as provided in section 40.8 of the MCMG. Any rewards and incentives programs must be consistent with section 100 of Chapter 4 of the Medicare Managed Care Manual.

Section 50.2 - Marketing/Sales Events

In addition to requirements in this section of the MCMG, the FIDA Plan must convene all educational and marketing events at sites within the plan's service area that are physically accessible to all Participants or potential FIDA Plan Participants, including persons with disabilities and persons using public transportation.

Section 50.3 - Personal/Individual Marketing Appointments

Since New York FIDA Plans are not allowed to market directly to individual potential FIDA Plan Participants, one-one-one appointments with potential FIDA Plan Participants are generally not permitted. We clarify, however, that if a current FIDA or non-FIDA Plan Participant of the organization proactively requests a one-on-one appointment and the FIDA Plan has a documented incoming request for the one-on-one appointment, the FIDA Plan may meet with the Participant subject to the requirements of section 50.3 of the MCMG.

Additionally, we clarify that, as described in Appendix 5 of New York's FIDA-specific Enrollment and Disenrollment Guidance (see https://www.cms.gov/Medicare-Medicaid-Coordination-Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/NYApp5101916.pdf), FIDA Plans may accept new enrollment requests directly from new-to-service individuals and may submit these to New York's enrollment broker using the U-file process.

We further clarify that home and other one-on-one visits by non-sales plan employees for purposes related to care coordination are not considered individual marketing appointments. We note that such individuals should never conduct marketing activity, as defined in section 20 of this guidance, but we clarify that non-sales plan employees may provide factual information about the benefits and products offered by FIDA Plans if individuals request it in the course of care coordination activities.

Section 60.1 - Provider-Initiated Activities

We clarify that the guidance in this section referring patients to other sources of information such as the "State Medicaid office" also applies to materials produced and/or distributed by New York's enrollment broker.

Section 60.4 - Plan/Part D sponsor Activities in the Healthcare Setting

In addition to the requirements of this section, we clarify that staff in health care settings such as, but not limited to, long-term care facilities, day care settings, and chronic and psychiatric hospitals for FIDA Plan-eligible individuals (post-stabilization) may provide residents meeting FIDA Plan eligibility criteria with an explanatory brochure for each FIDA Plan with which the facility contracts.

Section 70.1.2 - Documents to be Posted on Website

The requirements of this section apply with the following modifications:

- FIDA Plans will not be required to post the LIS Premium Summary Chart, as this document will not be applicable to FIDA Plans.
- Because MMCO is in the process of developing a Star Ratings system for MMP performance, FIDA Plans will not be subject to the Star Ratings requirements in the MMG. Therefore, FIDA Plans will not be required to post a CMS Star Ratings document on their websites.

Section 70.1.3 - Required Content

In addition to the requirements outlined in this section, FIDA Plans must also include on their websites a direct link to New York's enrollment broker. FIDA Plans must also include information on the potential for contract termination (as required under 42 CFR 422.111(f)(4)), and information that materials are published in alternate formats (e.g., large print, braille, audio). As provided in section 70.1.1 of the MCMG, plan websites must be 508 compliant, and FIDA Plans must attest that they comply with all applicable requirements when they submit their websites for review in HPMS.

FIDA Plans must also include a disclaimer, as provided in Appendix 2 of this guidance, on all marketing materials and on their website specifying the availability of the Participant Ombudsman to provide Participants with free assistance in handling any issues relating to accessing services. FIDA Plans must include the toll-free number and the website for the Participant Ombudsman.

Section 80.2 - Customer Service Call Center Hours of Operations

We clarify that FIDA Plans must operate a toll-free call center for both current and potential FIDA Plan Participants seven (7) days a week, at least from 8:00 a.m. to 8:00 p.m. ET, except as provided below. Customer service call center hours and days must be the same for all individuals regardless of whether they speak English, a non-English language, or use assistive devices for communication. During this time period, current and potential FIDA Plan Participants must be able to speak with a live customer service representative. FIDA Plans may use alternative technologies on Saturdays, Sundays, Federal and/or State holidays (except New Year's Day) in lieu of having live customer service representatives. For example, a FIDA Plan may use an interactive voice response (IVR) system or similar technologies to provide the required information listed in section 80.1 of the MCMG, and/or allow a Participant to leave a message in a voice mail box. A customer service representative must then return the call in a timely manner, no more than one (1) business day later. All other guidance in section 80.2 of the MCMG applies to FIDA Plans.

Section 80.3 - Informational Scripts

We clarify that informational calls to plan call centers that become marketing discussions, per the definition of marketing in section 20 of this guidance, may be conducted by plan staff provided such staff complies with the licensure requirements for marketing activity in section 110 of this guidance and the MCMG. Calls that become enrollment requests must be transferred to New York's enrollment broker.

Prior to transferring an informational call to New York's enrollment broker, the Participant must be informed he/she is being transferred. The FIDA Plan representative may remain on the line during the call to the enrollment broker for enrollment calls.

FIDA Plans should refer to section 80.7 of this guidance, as well as section 80.7 of the MCMG, for clarification of the types of activities conducted by a plan customer service representative that do not require the use of State-licensed marketing representatives. FIDA Plans must use a State-licensed (and, when required, appointed) marketing agent for any activity that meets the definition of marketing in section 20 of this guidance.

Section 80.4 - Telesales and Enrollment Scripts

Telesales scripts are considered marketing and must be submitted to CMS as outlined in section 90 of this guidance. The remainder of the guidance in this section on enrollment scripts does not apply to FIDA Plans because enrollment requests must be transferred to New York's enrollment broker.

Section 80.7 - Activities That Do Not Require the Use of State-Licensed Marketing Representatives

Consistent with section 80.7 of the MCMG, we clarify that in order to provide more than factual information, FIDA Plan outbound callers must be State-licensed (and, when required, appointed) marketing agents. FIDA Plans must use State-licensed (and, when required, appointed) marketing agents for any activity that meets the definition of marketing in section 20 of this guidance.

Section 90 - Tracking, Submission, and Review Process

Any references in this section of the MCMG, and in all subsections thereunder, to CMS in its role in reviewing marketing materials are also references to the State for purposes of FIDA Plan marketing material review.

Section 90.1 - Material Identification

The second paragraph of this section of the MCMG is modified as follows for FIDA Plans:

The material ID is made up of two parts: (1) MMP contract number, (i.e., H number) followed by an underscore; and (2) any series of alphanumeric characters chosen at the discretion of the FIDA Plan. Use of the material ID on marketing materials must be immediately followed by the status of either approved or accepted (e.g., H1234_drugx38 Approved). Please note that FIDA Plans should include an approved status only after the material is approved and not when submitting the material for review.

The remainder of section 90.1 of the MCMG applies to FIDA Plans, including the requirement that non-English and alternate format materials based on previously created materials may have the same material ID as the material on which they are based.

Section 90.1.1 - Materials Subject to Submission

CMS has developed a joint review process for MMP beneficiary materials under each Financial Alignment Initiative capitated model demonstration that combines State and CMS review requirements and parameters. Given these differences, CMS will continue to consider all CY 2019 FIDA Plan materials to be marketing materials as defined prior to the implementation of CMS-4182-F.⁴

Section 90.4 - Submission of Websites and Webpages for Review

The requirements of this section apply without modification. We note, however, that FIDA Plans should use State-specific MMP website codes. For more information about website codes, FIDA Plans should consult the Marketing Code Look-up functionality in the HPMS Marketing Module.

Section 90.5 - Submission of Multi-Plan Materials

This section does not apply to the FIDA Plans.

Section 90.6 - Status of HPMS Material

We clarify that, for purposes of FIDA Plan materials, there is no "deeming" of materials requiring either a dual review by CMS and the State or a one-sided State review, and materials remain in a "pending" status until the State and CMS reviewer dispositions match. Materials in a "pending" status are not approved for use in the market. However, CMS and State marketing reviewers have standard operating procedures for ensuring materials are reviewed in a timely manner and differences in dispositions are resolved expeditiously. Materials that require a CMS-only review deem after the respective 10- or 45-day review period. FIDA Plans may obtain more information about the specific review parameters and timeframes for marketing materials under the New York FIDA capitated financial alignment model demonstration in the Marketing Code Look-up functionality in the HPMS Marketing Module.

In addition to the guidance in this section, the FIDA Plan submitting modifications to a previously approved marketing material must submit a cover document that precisely lists all proposed wording changes to the previously approved marketing material. This will expedite the review and approval process.

We also note that the "non-marketing" status is not available for joint review process (JRP) marketing codes in HPMS for CY 2019. All other guidance in this section of the MCMG applies.

^{4 &}quot;Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE program," which may be found in the Federal Register published April 16, 2018 (see https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare).

Section 90.7 - Resubmitting Previously Disapproved Pieces

In addition to the requirements of this section, and in order to expedite the re-review and approval process, FIDA Plans resubmitting previously disapproved pieces must submit a cover document that precisely lists all proposed wording changes to the previously disapproved materials.

Section 90.8 - File & Use Process

We clarify that the File & Use certification for the FIDA Plan is included in the three-way contract. All other guidance in section 90.8 of the MCMG applies.

Section 100 - Required Materials

We clarify that CMS will continue to consider all CY 2019 MMP materials to be marketing materials as defined prior to the implementation of CMS-4182-F.⁵ As a result all marketing materials must be submitted in HPMS. All other portions of this section apply to MMPs.

Section 100.4 - List of Required Materials

This section is replaced with the following revised guidance:

Section 100.4 - List of Required Materials 42 CFR 417, 422, 423, 438

Model Materials

We clarify that marketing documents and marketing activities must reasonably accommodate persons with physical or communications-related disabilities, including individuals with cognitive, learning, and psychiatric disabilities. Language related to this requirement is incorporated throughout this guidance.

We note that materials FIDA Plans create should take into account the reading level requirements established in the three-way contract. Available FIDA Plan-specific model materials reflect acceptable reading levels. Current Part D models are acceptable for use as currently provided, and the FIDA Plans must add required disclaimers in Appendix 2 of this guidance, as appropriate. Adding required FIDA Plan disclaimers to Part D models does not render the documents non-model when submitted for review or accepted as File & Use materials.

We refer FIDA Plans to the following available model materials:

 FIDA Plan-specific model materials, including, but not limited to, an Annual Notice of Changes (ANOC); a Summary of Benefits (SB); Evidence of Coverage (EOC) (Participant Handbook); comprehensive integrated formulary (List of Covered Drugs);

⁵ "Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE program," which may be found in the Federal Register published April 16, 2018 (see https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare).

combined Provider and Pharmacy Directory; single Participant ID Card; the integrated coverage determination notice and other appeals and grievances notices; welcome letters and other plan-delegated enrollment notices; and FIDA-specific prescription drug explanation of benefits (EOB), transition notice, prescription transfer notice, and excluded provider notice: https://www.cms.gov/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPMarketingInformationandResources.html.

- Part D appeals and grievances models (including those in Chapter 18 of the Prescription Drug Benefit Manual): https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/PlanNoticesAndDocuments.html.
- Part C appeals and grievances notices and models (including those in Chapter 13 of the Medicare Managed Care Manual): http://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Notices.html.
- MMP-specific ANOC/EOC (Participant Handbook) errata model:
 https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPMarketingInformationandResources.htmlOffice/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html.

Required Materials and Instructions for FIDA Plans

Below is a list of required materials for FIDA Plans. In addition, we provide high-level information for each material. Guidance (as noted) should be reviewed as applicable. Additionally, FIDA Plans should consult the HPMS Marketing Code Look-up functionality for specific codes and instructions for uploading required materials.

FIDA Plans may enclose additional benefit/plan operation materials with required materials, unless specifically prohibited in instructions or prohibited as noted below for each material. Additional materials must be distinct from required materials and must be related to the FIDA Plan in which the Participant is enrolled.

Annual Notice of Changes (ANOC)	
To Whom Required:	Must be provided to current FIDA Plan Participants, including those with October 1, November 1, and December 1 effective dates.

Annual Notice of Changes (ANOC)	
Timing:	 FIDA Plans must send for Participant receipt no later than September 30 of each year. (Note: The ANOC must be posted on the FIDA Plan website by October 15.) Plan Participants with October 1, November 1, and December 1 enrollment effective dates must receive the ANOC for the upcoming year by one (1) month after the effective date of enrollment but not later than December 15.
Method of Delivery:	Hard copy, or electronically, if Participant has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.
HPMS Timing and Submission: Format Specification:	 Code 16708. Must be submitted prior to mailing ANOCs. NY FIDA MMP model required for current Contract Year. Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	 Actual Mail Dates (AMDs) and number of recipients (not the number of ANOCs mailed) must be entered into HPMS within 15 days of mailing. This includes mail dates for alternate materials. MMPs that mail in waves should enter the AMD for each wave. MMPs may enter up to ten waves of mailings. For instructions on meeting this requirement, refer to the <i>Update AMD/Beneficiary Link/Function</i> section of the Marketing Review Users Guide in HPMS. Note: For a single mailing to multiple recipients, as allowed under section 100.1 of the MCMG, the MMP should enter an AMD that reflects the number of recipients, not the number of ANOC/EOCs (Participant Handbooks), mailed. Plans may include the following with the ANOC: Summary of Benefits (SB) Provider and Pharmacy Directory EOC (Participant Handbook) Formulary (List of Covered Drugs) Form allowing Participants to "opt in" to receiving their upcoming ANOC and EOC (Participant Handbook) via email. No additional plan communications unless otherwise directed.
Translation Required (5% Threshold):	Yes.

ANOC and EOC (Participant Handbook) Errata	
To Whom Required:	Must be provided when plan errors are found in the ANOC or EOC (Participant Handbook) and sent to current FIDA Plan Participants.
Timing:	Must send to Participants immediately following CMS approval.
Method of Delivery:	Hard copy, or electronically, if Participant has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.
HPMS Timing and	Code 16705 for ANOC Errata.
Submission:	 Code 16758 for EOC (Participant Handbook) Errata. ANOC Errata must be submitted by October 15.
	EOC (Participant Handbook) Errata must be submitted by November 15.
Format Specification:	Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	FIDA Plans must use an errata notice to notify Participants of plan errors in their original documents. We clarify that errata notices should only be used to notify Participants of plan errors in plan materials.
	Note: Any mid-year changes, including but not limited to mid-year legislative benefit additions or removals and changes in enrollment policies, should be communicated to current Participants consistent with the "Mid-Year Change Notification" guidance in this section. The HPMS errata submission process should not be used for mid-year changes to materials that are not due to plan error. Instead plans should use the HPMS Marketing Module replacement function for these changes.
Translation Required (5% Threshold):	Yes.

Coverage/Organization Determination, Discharge, Appeals and Grievance Notices	
To Whom Required:	 Must be provided to Participants who have requested an appeal or have had an appeal requested on their behalf. Grievances may be responded to electronically, orally, or in writing.
Timing:	Provided to Participants (generally by mail) on an ad hoc basis, based on required timeframes in three-way contract.
Method of Delivery:	Hard copy, or electronically, if Participant has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.
HPMS Timing and Submission:	 Code 16720 for NY MMP State-specific appeals notices. Various codes for other CMS required notices. Refer to HPMS Marketing Code Look-up functionality for NY MMP codes.
Format Specification:	 NY FIDA MMP models - standardized model; a non-model document is not permitted. Other CMS models - modifications permitted.
Guidance and Other Needed Information:	Three-way contract, Chapter 13 of the Medicare Managed Care Manual, and Chapter 18 of the Medicare Prescription Drug Benefit Manual.
Translation Required (5% Threshold):	Yes.

Evidence of Coverage (EOC) / Participant Handbook	
To Whom Required:	Must be provided to all FIDA Plan Participants.
Timing:	 Must send to current FIDA Plan Participants for receipt by October 15 of each year. Must send to Participants who opt in to the FIDA Plan for receipt no later than eight (8) calendar days from receipt of CMS confirmation of enrollment or by last day of the month prior to the effective date, whichever is later. Must send to Participants who are passively enrolled for receipt by the end of the month preceding the month the enrollment will take effect (e.g., must be received by a Participant by March 31 for an April 1 effective enrollment date). New Participants with an effective date of October 1, November 1, or December 1 should receive both an EOC
	(Participant Handbook) for the current contract year, as well as an EOC (Participant Handbook) document for the upcoming contract year. We clarify that, for these Participants, the ANOC may be included in the EOC (Participant Handbook) or provided separately, as well as the formulary (List of Covered Drugs) (or a distinct and separate notice alerting Participants how to access or receive the formulary), and the Provider and Pharmacy Directory (or a distinct and separate notice alerting Participants how to access or receive the directory) for the upcoming year, must be received by one (1) month after the effective date of enrollment, but not later than December 15.
Method of Delivery:	Hard copy EOC (Participant Handbook) or via Electronic Notice of Documents (consistent with section 100.2.1 of the MCMG) or electronically, if Participants has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.
HPMS Timing and	• Code 16707.
Submission:	Submitted prior to October 15 of each year.
Format Specification:	 NY FIDA MMP model required for current Contract Year. Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	No additional information.
Translation Required (5% Threshold):	Yes.

Excluded Provider Letter	
To Whom Required:	Provided to Participants when a sponsor has excluded a prescriber or pharmacy participating in the Medicare program
	based on an Office of Inspector General (OIG) exclusion.
Timing:	Provided to Participants on an ad hoc basis.
Method of Delivery:	Hard copy, or electronically, if Participants has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.
HPMS Timing and Submission:	Code 16735.
Format Specification	Model provided; modifications permitted.
Guidance and Other Needed Information:	https://oig.hhs.gov/fraud/exclusions.asp
Translation Required (5% Threshold):	Yes.

Explanation of Benefits (EOB) – Part D	
To Whom Required:	Must be provided anytime a Participant utilizes their prescription drug benefit.
Timing:	Sent at the end of the month following the month when the benefit was utilized.
Method of Delivery:	Hard copy, or electronically, if Participant has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.
HPMS Timing and Submission:	Code 16734.
Format Specification:	 NY FIDA MMP Rx-only EOB model required for current Contract Year. Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	Three-way contract, Medicare Prescription Drug Benefit Manual Chapters 5 and 6, and HPMS code usage instructions.
Translation Required (5% Threshold):	Yes.

Formulary (List of Covered Drugs)	
To Whom Required:	Must be provided to all FIDA Plan Participants.
Timing:	 Must be sent to current Participants of plan for receipt by October 15 of each year. Must send to Participants who opt in to the FIDA Plan for receipt no later than eight (8) calendar days from receipt of
	CMS confirmation of enrollment or by last day of the month prior to the effective date, whichever is later.
Method of Delivery:	Hard copy, or via Electronic Notice of Documents (consistent with section 100.2.1 of the MCMG) or electronically, if Participant has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.
HPMS Timing and Submission:	Code 16702.
Format Specification:	Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	 The FIDA Plan must make available a comprehensive integrated formulary (List of Covered Drugs) that includes Medicare and Medicaid outpatient prescription drugs and pharmacy products provided under the plan. OTC items and/or supplemental benefits that are in excess of
	 Medicaid requirements may not be included in this document. The FIDA Plan is only permitted to make available a comprehensive, not abridged, formulary (List of Covered Drugs).
Translation Required (5% Threshold):	Yes.

Integrated Denial Notice	
To Whom Required:	Any Participant with an adverse benefit determination.
Timing:	Provided to Participants (generally by mail) on an ad hoc basis, at least ten (10) days in advance of any adverse benefit determination.
Method of Delivery:	Hard copy, or electronically, if Participant has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.
HPMS Timing and Submission:	Code 16719.
Format Specification:	 NY FIDA MMP model required for current Contract Year. Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	Three-way contract.
Translation Required (5% Threshold):	Yes.

	Mid-Year Change Notification to Enrollees
To Whom Required:	Must be provided to all applicable Participants when there is a mid-year change in benefits, plan rules, formulary, provider network, or pharmacy network.
Timing:	Ad hoc, based on specific requirements for each issue.
Method of Delivery:	Hard copy, or electronically, if Participant has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.
HPMS Timing and Submission:	Various codes. Refer to HPMS Marketing Code Look-up functionality for NY MMP codes.
Format Specification:	Model not available; must include required content.
Guidance and Other Needed Information:	 Information about non-renewals or service area reductions may not be released to the public, including current Participants, until model notice is received from CMS. FIDA Plans may elect to share Non-Renewal and Service Area Reduction (NR/SAR) information only with first tier, downstream, and related entities (FDRs) or anyone that the MAO does business with (i.e., contracted providers). Additional NR/SAR notice information can be found in the annual "Non-Renewal and Service Area Reduction Guidance and Enrollee Notification Models" HPMS memo. If a non-model document is created the document must contain all the elements in the model.
Translation Required (5% Threshold):	Yes.

Part D Transition Letter		
To Whom Required:	Must be provided when a Participant receives a transition fill for a non-formulary drug.	
Timing:	Must be sent within three (3) days of adjudication of temporary transition fill.	
Method of Delivery:	Hard copy.	
HPMS Timing and	Code 16738.	
Submission:		
Format Specification:	Model provided; modifications permitted.	
Guidance and Other	Medicare Prescription Drug Benefit Manual, Chapter 6, Section	
Needed Information:	30.4.10.	
Translation Required (5% Threshold):	Yes.	

Participant ID Card		
To Whom Required:	Must be provided to all FIDA Plan Participants.	
Timing:	 Must send to Participants who opt in to the FIDA Plan for receipt no later than eight (8) calendar days from receipt of CMS confirmation of enrollment or by last day of the month prior to the effective date, whichever is later. Must also be provided to all Participants if information on existing card changes. 	
Method of Delivery:	Must be provided in hard copy. In addition to the hard copy, plans may also provide a digital version (e.g., app).	
HPMS Timing and Submission:	Code 16710.	
Format Specification:	Standardized model; a non-model document is not permitted.	
Guidance and Other Needed Information:	FIDA Plans must issue a single Participant ID Card meeting these requirements for all services offered under the plan. Separate pharmacy and health benefits ID cards are not permitted.	
Translation Required (5% Threshold):	No.	

Plan-Delegated Enrollment and Disenrollment Notices		
To Whom Required:	Must be provided as outlined in National Enrollment/Disenrollment Guidance for States & MMPs.	
Timing:	Varies; must follow required timeframes as outlined in National Enrollment/Disenrollment Guidance for States & MMPs.	
Method of Delivery:	Hard copy, or electronically, if Participant has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.	
HPMS Timing and Submission:	Code 16747.	
Format Specification:	 NY FIDA MMP model required for current Contract Year. Standardized model; a non-model document is not permitted. 	
Guidance and Other Needed Information:	 National Enrollment/Disenrollment Guidance for States & MMPs. 	
	 NY FIDA Enrollment Guidance Appendix 5. FIDA Plans must use the Marketing Code Look-up functionality in the HPMS Marketing Module, along with the enrollment/disenrollment guidance to determine the most appropriate code for its submissions. 	
Translation Required (5% Threshold):	Yes.	

Prescription Transfer Letter		
To Whom Required:	When a Part D sponsor requests permission from a Participant to fill a prescription at a different network pharmacy than the one currently being used by the Participant.	
Timing:	Ad hoc.	
Method of Delivery:	Hard copy.	
HPMS Timing and Submission:	Code 16736.	
Format Specification:	Model provided; modifications permitted.	
Guidance and Other Needed Information:	The model notice should only be used when the transfer of the prescription is not initiated by the Participant (or someone on his or her behalf).	
Translation Required (5% Threshold):	Yes.	

Provider and Pharmacy Directory		
To Whom Required:	Must be provided to all current FIDA Plan Participants.	
Timing:	 Must be sent to current Participants of Plan for receipt by October 15 of each year. Must send to Participants who opt in to FIDA Plans for receipt no later than eight (8) calendar days from receipt of CMS confirmation of enrollment or by last day of the month prior to the effective date, whichever is later. Must send to Participants who are passively enrolled for receipt no later than 30 calendar days prior to enrollment. Must be provided to current Participants upon request, within three (3) business days of the request. Must update directory information any time they become aware of changes. All updates to the online provider and pharmacy directory are expected to be completed within 30 days of receiving information. Updates to hard copy of the provider and pharmacy directory must be completed within 30 days; however, a hard copy directory that includes separate updates via addenda is considered up-to-date. 	
Method of Delivery:	Hard copy or via Electronic Notice of Documents (consistent with section 100.2.1 of the MCMG) or electronically, if Participant has opted into receiving electronic version as permitted in section 100.2.2 of the MCMG.	
HPMS Timing and Submission:	Code 16703.	
Format Specification:	 NY FIDA MMP model required for current Contract Year. Standardized model; a non-model document is not permitted. 	

Provider and Pharmacy Directory		
Provider and Pharmacy Directory		
Guidance and Other Needed Information:	 FIDA Plans are required to make available a single combined Provider and Pharmacy Directory. Separate pharmacy and provider directories are not permitted. FIDA Plans may print separate directories for primary care physicians (PCPs) and specialists provided both directories are made available to Participants at the time of enrollment. The single combined Provider and Pharmacy Directory must include all network providers and pharmacies, regardless of whether they provide Medicare, Medicaid, or additional benefits. For FIDA Plans with multi-county service areas, the combined Provider and Pharmacy Directory may be provided for all providers by county, provided the directory includes a disclaimer that the directory only includes providers in that particular county (or counties), that a complete directory is available on the plan's website, and that the Participant may contact the plan's customer service call center to request assistance with locating providers in other counties or to request a complete hard copy Provider and Pharmacy Directory. FIDA Plans must submit directory updates and/or addenda pages in HPMS, and these documents are reviewed consistent with the parameters for the NY FIDA Provider and Pharmacy Directory marketing code. As applicable, refer to the language and guidelines issued in the August 16, 2018, HPMS memorandum, "Pharmacy Directories and Disclaimers" for the pharmacy portion of the combined directory. 	
Translation Required	Yes.	
(5% Threshold):		

Scope of Appointment (SOA)		
To Whom Required:	Must be documented for all marketing activities, in-person, telephonically, including walk-ins to FIDA Plan or agent offices.	
Timing:	Prior to the appointment.	
Method of Delivery:	Beneficiary signed hard copy, telephonic recording, or electronically signed.	
HPMS Timing and Submission:	Code 16754.	
Format Specification:	No model required, must include required content.	
Guidance and Other Needed Information:	 The following requirements must be on the scope of appointment form or on the recorded call: Product types to be discussed Date of appointment Beneficiary and agent contact information Statement stating there is no obligation to enroll, current or future Medicare enrollment status will not be impacted, and automatic enrollment will not occur. A new SOA is required if, during an appointment, the beneficiary requests information regarding a different plan type than previously agreed upon. 	
Translation Required (5% Threshold):	Yes.	

Summary of Benefits (SB)			
To Whom Required:	Optional with the ANOC and as requested for other Participants.		
Timing:	Must be available by October 15 of each year but can be released as early as October 1 of each year.		
Method of Delivery:	Hard copy.		
HPMS Timing and Submission:	Code 16700. Submitted prior to October 15 of each year.		
Format Specification:	 NY FIDA MMP model required for current Contract Year. Standardized model; a non-model document is not permitted. 		
Guidance and Other Needed Information:	 The SB must contain a concise description of the important aspects of enrolling in the plan, as well as the benefits offered under the plan, including applicable conditions and limitations and any other conditions associated with receipt or use of benefits. Appendix 5 of the MCMG, Summary of Benefit Instructions, does not apply. 		
Translation Required (5% Threshold):	Yes.		

Welcome Letter		
To Whom Required:	Must be provided to all new FIDA Plan Participants.	
Timing:	Must send to Participants who opt in to the FIDA Plan for receipt no later than eight (8) calendar days from receipt of CMS confirmation of enrollment or by last day of the month prior to the effective date, whichever is later.	
Method of Delivery:	Hard copy.	
HPMS Timing and Submission:	Code 16701.	
Format Specification:	NY FIDA model required for Contract Year.	
Guidance and Other Needed Information:	 Must contain 4Rx information consistent with the model. National Enrollment/Disenrollment Guidance for States & MMPs section 30.5.1. 	
Translation Required (5% Threshold):	Yes.	

Required Materials for New FIDA Plan Participants

The following table summarizes the required materials, and timing of receipt, for new FIDA Plan Participants.

Table 1. Required Materials for New Participants

Enrollment Mechanism	Required Materials for New Participants	Timing of Participant Receipt
Passive Enrollment	 Welcome letter Formulary (List of Covered Drugs) (or a distinct and separate notice alerting Participants how to access or receive the formulary) Provider and Pharmacy Directory (or a distinct and separate notice alerting Participants how to access or receive the directory) SB 	30 calendar days prior to the effective date of enrollment

Enrollment Mechanism	Required Materials for New Participants	Timing of Participant Receipt
Passive Enrollment	 Participant ID Card EOC (Participant Handbook) (or a distinct and separate notice alerting enrollees how to access or receive the EOC (Participant Handbook)) 	No later than the day prior to the effective date of enrollment
Opt-in enrollment (with enrollment confirmation received more than eight (8) calendar days before the end of the month) ⁶	 Welcome letter Formulary (List of Covered Drugs) (or a distinct and separate notice alerting Participants how to access or receive the formulary) Provider and Pharmacy Directory (or a distinct and separate notice alerting Participants how to access or receive the directory) Participant ID Card EOC (Participant Handbook) (or a distinct and separate notice alerting enrollees how to access or receive the EOC (Participant Handbook)) 	No later than the last day of the month prior to the effective date of enrollment

⁶ The FIDA Plan should refer to the date of the Daily Transaction Reply Report (DTRR) that has the notification to identify the start of the eight (8) calendar-day timeframe.

Enrollment Mechanism	Required Materials for New Participants	Timing of Participant Receipt
Opt-in enrollment (with enrollment confirmation received less than eight (8) calendar days before the end of the month) ⁶	 Welcome letter Formulary (List of Covered Drugs) (or a distinct and separate notice alerting Participants how to access or receive the formulary) Provider and Pharmacy Directory (or a distinct and separate notice alerting Participants how to access or receive the directory) Participant ID Card EOC (Participant Handbook) (or a distinct and separate notice alerting enrollees how to access or receive the EOC (Participant Handbook)) 	No later than eight (8) calendar days from receipt of the confirmation of enrollment

Section 110 - Agent/Broker Activities, Oversight, and Compensation Requirements

The provisions in this section of the MCMG and all its subsections applicable to independent agents/brokers do not apply to FIDA Plans since the use of independent agents/brokers is not permitted. All FIDA Plan enrollments are processed by New York's enrollment broker. We clarify that CMS and NYSDOH do not regulate compensation of employed agents for FIDA Plans.

We also clarify that FIDA Plan staff conducting marketing activity of any kind, as defined in section 20 of this guidance, must be licensed in the State (and, when required, appointed) as an insurance broker/agent.

Appendix 2 - Disclaimers

The disclaimer language in the following table replaces the language in Appendix 2 of the MCMG.

Table 2. State-specific MMP Disclaimers

Disclaimer	Required MMP Disclaimer Language	MMP Disclaimer Instructions
Federal Contracting	<plan's legal="" marketing="" name="" or=""> is a managed care plan that contracts with both Medicare and the New York State Department of Health (Medicaid) to provide benefits of both programs to Participants through the Fully-Integrated Duals Advantage (FIDA) Demonstration.</plan's>	Required on materials as described in the "Applicable Documents and Notes" column in Appendix 2 of the MCMG.
Benefits – "This is not a complete list"	This is not a complete list. The benefit information is a brief summary, not a complete description of benefits. For more information contact the plan or read the <plan name=""> Participant Handbook.</plan>	Required on the SB and all materials with 10 or more benefits except the EOC (Participant Handbook).
Availability of Non-English Translations	ATTENTION: If you speak <language disclaimer="" of="">, language assistance services, free of charge, are available to you. Call <participant and="" days="" hours="" numbers,="" of="" operation="" phone="" services="" tdd="" toll-free="" tty="">. The call is free.</participant></language>	Required on materials as described in the "Applicable Documents and Notes" column in Appendix 2 of the MCMG.
Plan Online Enrollment Center	This disclaimer does not apply to MMPs.	N/A
Star Ratings	This disclaimer does not apply to MMPs.	N/A
Materials Developed by a Third Party	This disclaimer does not apply to MMPs.	N/A
Non-plan and Non-health information	Neither Medicare nor New York Medicaid has reviewed or endorsed this information.	Required on non-plan and non-health related information once prior authorization from the Participant is granted to receive materials.

Disclaimer	Required MMP Disclaimer Language	MMP Disclaimer Instructions
Participant Ombudsman	The State of New York has created a Participant ombudsman program called the Independent Consumer Advocacy Network (ICAN) to provide Participants free, confidential assistance on any services offered by <plan name="">. ICAN may be reached toll-free at 1-844-614-8800 or online at icannys.org. (TTY users call 711, then follow the prompts to dial 844-614-8800.)</plan>	Required on all marketing materials (except radio ads) and required on the plan's website.

Appendix 3 - Pre-Enrollment Checklist

This appendix does not apply to FIDA Plans since all enrollments are submitted by New York's enrollment broker.

Appendix 7 - Use of Medicare Mark for Part D Sponsors

We clarify that FIDA Plans have been required to sign a licensing agreement to use the official Medicare Mark as part of the three-way contract, rather than through the HPMS contracting module. All other guidance in Appendix 7 of the MCMG applies.