



A National Nonprofit Leadership Organization

SNP ALLIANCE COMMENTS
CMS Interoperability Rule and HHS ONC Cure's Act Rule Proposals
Related to Dually Eligible Beneficiaries and SNP Populations

Please note, these comments are meant to be read jointly for both rules. However primary comments for each rule are found as follows:

Interoperability Rule: Pages 1-22.
ONC Cure's Act Rule: Pages 22-24.

Submitted via Federal e-Rulemaking Portal: <http://www.regulations.gov>

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Seema Verma, Administrator
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RE: RIN 0938-AT79 CMS-9115-P: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers

Dear Administrator Verma:

The SNP Alliance is pleased to provide comments to CMS regarding the proposed rule on Interoperability and Patient Access for Medicare Advantage Organizations and Medicaid Managed Care Plans and Medicaid Agencies (84 FR 7610, March 4, 2019).

The SNP Alliance is a national, non-profit leadership association addressing the needs of high-risk and high-cost populations through specialized managed care. We represent over 390 special needs plans (SNPs) and Medicare-Medicaid demonstration plans (MMPs), with over 1.9 million enrolled members. Our primary goals are to improve the quality of services and care outcomes for the complex populations served and to advance integration for those dually eligible for Medicare and Medicaid. Many of our member health plans have been leaders in the promotion of interoperability strategies. They are aware of the painstaking work required to develop and exchange health information across settings, services, providers, and payers, to improve the coordination and integration of care.

While we applaud the overall vision laid out in this rule and see some exciting opportunities ahead in certain proposed requirements, we also have serious concerns about this rule. Our main recommendations are outlined as follows:

- Recommendation 1: Delay Implementation to Assure Data Protection, Readiness and Consider Additional Cost Implications**
- Recommendation 2. Utilize TEFCA Platform for Exchanges Between Payers and Revise USCDI Data Elements to Reflect Health Plan Functions**
- Recommendation 3. Make USCDI Modifications to Reflect Dual Eligible Health Plan Enrollments**
- Recommendation 4. Enhance State Submission of MMA Files with Additional Enrollment Information**
- Recommendation 5. Interface with Stars and Quality Management Systems (QMS)**
- Recommendation 6. Improving the Medicare-Medicaid Dually Eligible Experience RFI Responses**

Summary of SNP Alliance Comments and Recommendations:

Introduction

The SNP Alliance appreciates the opportunity to comment on this highly ambitious rule. We are impressed with CMS' vision and foresight in developing this rule as well as its willingness to tackle the complex tasks involved and the coordination with HHS and ONC that are being displayed. We also appreciate the opportunities provided under the proposed rule for improvement of care coordination through data sharing among payers and providers as well as between payers which we view as especially important in the case of dually eligible beneficiaries who are subject to conflicts and confusion when their care is divided up among payers without alignment of enrollment and clinical and financial incentives.

While we support the goals of this proposed rule, there is a large gap between the comprehensive vision outlined here and the current state of the art. The timeframes and scope are not realistic and do not consider the current capability or capacity of the many affected entities including individual providers, states, and health plans to comply with all of these requirements. The very short timelines proposed are an indication that CMS may not have fully conducted an environmental analysis. The timeframes severely underestimate the level of resources, technology and human interface, including hardware, applications, training, and other infrastructure development that will be required. There is a mismatch between the functionalities which are currently in use and those which will be necessary to achieve the goals of this proposal.

Based on information shared with us, we do not believe that current provider EHR platforms, health plan data systems, and other necessary technologies are sufficiently evolved to support these concepts. Considerable time and financial investment across health plans and providers, as well as by states and other key stakeholders will be required. Without such investment, serious harm could result. The lack of protection of beneficiaries' private information as well as the potential for misinformation being transmitted along a chain of organizations are two adverse events that can be predicted. We have serious concerns about the risk of proliferation of data privacy breaches and the potential for perpetuation of errors in PHI that may be exacerbated under this system. We therefore strongly recommend delay of implementation, while the necessary environmental scan can be done, providing a greater understanding of infrastructure and capacity building needed, and while organizations and states build key foundational components to support such interoperability.

Recommendation 1: Delay Implementation to Assure Data Protection, Readiness and Consider Additional Cost Implications

Extend Timeframes. CMS should extend its effective dates to accommodate the plethora of required elements and extensive foundational work that will be required in order to implement these new rules. This includes but is not limited to:

- finding qualified Application Programming Interface (API) developers which are admittedly in short supply,
- ensuring that there are standards for such developers through certification and oversight,
- assuring a robust API security strategy and control architecture, which is evolving for most industries, including health plans,
- developing use cases for health plan level data including non-health care transactions (e.g., home modifications) that are important to users of health plan data,
- developing API interfaces with TEFCA data sources,
- certifying developing and implementing overall regulatory and oversight structures for each segment of the industry included,
- making infrastructure and systems changes to support the functionalities proposed at both the provider and payer levels, and
- adequate testing of the myriad of interactions involved in these changes prior to full implementation.

CMS could consider phasing in portions of these requirements as required elements and foundational work is completed or beginning with additional pilot projects for some elements. In the meantime, we recommend that CMS continue working on development of this comprehensive vision by considering stakeholder comments to this proposal, engaging stakeholders in each sector around issues specific to them, developing additional plan level use cases, conducting additional testing, further assessing plan and provider readiness and HIE capabilities, and obtaining direct consumer reactions and input from a variety of subpopulations.

This is a unique and exciting opportunity for significant change across the entire health care system and we believe that, if the necessary foundational development occurs, it will avoid unintended negative consequences which could up-end the whole intent.

API Developer Standards and Certification Process and Modification of Open API Process. We recommend that CMS develop and implement a certification process for APIs and third party administrators including oversight and enforcement standards and penalties for violations, and additional standards that prohibit APIs, third party administrators, payers, or providers from sale or use of shared data and access tools in any manner for marketing, competitive advantage or rate purposes. CMS should assure there is a robust API security strategy and control architecture in place prior to implementation. Such strategies are still in early evolutionary stages for most industries, including health plans,

In addition, prior to implementation of use of APIs, we recommend that CMS conduct testing to provide additional assurance that the APIs and third-party administrators involved in consumer facing applications will safeguard PHI. Further, CMS should develop additional guidance and specifications to all parties to assure that these developers and sponsors are capable of producing APIs and third-party software that accommodate intricate policy differences across states in protection of PHI for behavioral health and substance abuse or other local requirements. This may necessitate reconsidering the open API process by reducing or consolidating API developers, plan APIs and third-party applications approved for use by

consumers to connect to health plan APIs and modifying privacy agreements to accommodate special needs of consumer users such as language, literacy and health literacy barriers.

Cost Impact and Rate Setting. While we generally support the direction CMS is moving, we remain concerned that CMS may be significantly underestimating the state of provider and plan capacity and readiness to accommodate these requirements. Therefore, we also request that CMS ensure that cost impacts of this rule be fully enumerated and considered in rate setting. These costs include:

- additional modification and development of (as currently proposed) multiple APIs,
- additional required testing,
- ongoing monitoring and evaluation of third-party connections to APIs at the payer/health plan level,
- infrastructure and other system changes needed to accommodate changes in methods of collecting and maintaining provider-based data at the health plan level,
- interface costs by vendors passed to providers and plans, and
- additional costs related to consumer education including costs for reaching culturally diverse groups and those with health literacy barriers.

We also believe it is essential that CMS evaluate the cost impact based on the size of health plans. We believe the implementation costs will have a proportionately larger impact on small health plans due to the portion of implementation costs that are fixed.

Recommendation 2. Utilize TEFCA Platform for Exchanges Between Payers and Revise USCDI Data Elements to Reflect Health Plan Data and Functions

Modify Payer to Payer Exchange Strategy. While we welcome the opportunity for clearer health plan pathways for exchange of patient information between payers, the proposed open API process appears to duplicate the TEFCA platform and strategies already being worked on and proposed elsewhere. We recommend that CMS modify its strategy to focus on use of the TECFA process for these plan-to-payer and payer-to-payer interoperability purposes rather than using the open API approach as yet another intermediary between health plans. CMS could use a pilot project to test these needed modifications prior to implementation.

In fact, the health plan may not be the appropriate or most efficient aggregator, repository or source of some of the required data compared to the TEFCA approach. Using the health plan as aggregator of 5 years of data for each member may be duplicative and confusing if the source of that data varies between previous health plans or between other entities functioning as part of a TEFCA arrangement and because health plans do not currently house all of the necessary USCDI data elements. Further, the volume involved in warehousing 5 years of data will be very costly and less efficient for all compared to the TECFA approach.

The proposed requirement also raises questions of what is the appropriate source of the various required data elements. There is a real possibility of conflicting and duplicative data carried over from secondary sources. How will any of these data elements be updated and verified?

In addition, the SNP Alliance is concerned that the use cases upon which such data specifications are currently built (which are largely provider-based data) may not be relevant to the manner in which health plans actually collect and maintain clinical and other data, leading to unintended consequences and confusion for beneficiaries. We anticipate that some data will be out of date, some data (such as lab results) may not be consistently reported or collected by plans/payers, clinical notes may be restricted for certain services, and some self-reported data may not be reliable or current due to beneficiaries' cognitive

impairments and/or shifting medical, supportive, and behavioral health priorities, based on the individual's current status. This is particularly true for special needs populations—persons with high care complexity and heavier social determinant of health risk factors.

Redact Cost Data that Can Reveal Proprietary Fee Schedules. The SNP Alliance recommends that data that could reveal proprietary fee schedules should not be required to be shared through this API process. As stated earlier, standards should be in place to prohibit providers or third-party administrators from using these data for competitive advantage to drive rates or for sales. There should be prohibitions about such use and safeguards around marketing or other use of competitive information.

Revise USCDI Data Elements Required for Payer to Payer Exchange. While the TEFCA platform would be the best and likely most efficient payer to payer data source and platform for retaining and sharing the required USCDI information, there will still be need for health plans to play a role in payer to payer data exchange for functions such as prior authorizations, transitions, care coordination, coverage issues, utilization review, enrollment and disenrollment status and dates, quality measurement and management and certain health plan operational functions. Therefore, we also recommend that CMS reconsider whether the USCDI dataset (or which of its elements) are the most appropriate for meaningful health plan data sharing.

Develop and Test or Pilot Health Plan Payer to Payer Based Use Cases. Due to the differences in functionality between health plans and providers, CMS cannot assume that use cases built for provider EHR/data transfers will translate to the best data sets and use cases for data needed for payer to payer transactions, or that the storing and access to data within payers is the same as it is for providers. We particularly note the range of health, social supports, long-term care, and behavioral health conditions and services for integrated Medicare and Medicaid plans and D-SNPs with Medicaid MLTSS or behavioral health contracts which may not be fully covered in the USCDI dataset.

Therefore, CMS should develop and test health plan use cases specific to health plan operations such as those that would support transfers needed for service authorizations and transitions as well as development of quality metrics, to ensure that standardized functions most essential to consumers are supported. CMS can incorporate what is learned from these health plan specific use cases to provide additional guidance for payer to payer and health plan data mapping requirements or could incorporate them into a payer to payer pilot prior to implementation. There is legitimate concern that implementation without such testing or piloting could seriously confuse consumers.

Recommendation 3. Make USCDI Modifications to Reflect Dual Eligible Health Plan Enrollments

The SNP Alliance welcomes the potential for expanding secure and more standardized data sharing mechanisms between Medicare and Medicaid payers for care coordination purposes. We look forward to opportunities to utilize these mechanisms to improve and simplify access and coordination of care for dually eligible populations across both Medicare and Medicaid as envisioned in Section V. of the preamble.

Remove Cost Information from USCDI Elements. However, as stated earlier, the SNP Alliance joins with other commenters to recommend that data that could reveal proprietary fee schedules should not be required to be shared and that prohibitions be included to prevent providers, payers or any other third party administrators from using this data for competitive advantage to drive rates or for potential marketing of competitive information.

Include Plan Enrollment Information in the Payer to Payer Data Exchange. The SNP Alliance strongly recommends that the specified information requirements for data exchange between payers be amended to include data elements and/or information related to a beneficiaries' health plan enrollment, including the type of health plan payer (Medicaid, Medicare Advantage, freestanding PDP, D-SNP, ISNP and CSNP or other payers as identified by CMS) as well as an individual's enrollment and disenrollment dates, all of which are essential to appropriate and accurate management, identification and transfer of member medical records over time, and is necessary information for enrollees as well as for compliance with HIPAA requirements.

The SNP Alliance is concerned that the data sharing provisions required between payers under this rule as well as under the new related ONC rule appear to be limited to the USCDI elements and does not contain any mention of provision of health plan payer and enrollment source or enrollment and disenrollment dates, which would be required for closer coordination of care between Medicare and Medicaid for dually eligible populations as well as for sharing of health information between any payers as proposed. If this information is implied somewhere in the process for the exchange mechanism, it should be expressly included in the rule for clarity instead, and if not implied, we strongly recommend that it be added to the core USCDI elements included in the USCDI exchange between health plan payers or otherwise explicitly provided along with standardized requirements for exchange.

Many D-SNPs struggle with the lack of access to regular information on payer source for the Medicaid services provided to their members such as MLTSS (managed long-term services and supports) and behavioral health services. This is especially a problem in states that have not chosen to or don't have the capacity to coordinate alignment of enrollment into the same plan for both Medicare and Medicaid or to provide this data to D-SNPs. Thus, Medicaid MCOs are often not sure of where their members are enrolled for Medicare benefits, and Medicare D-SNPs are not sure where their members are enrolled for Medicaid MLTSS and or behavioral health benefits. We also hear from states that they do not have an easily accessible source of data for where their Medicaid beneficiaries are enrolled for Medicare, making coordination of care more difficult. We are hopeful that the new payer to payer data sharing requirement could begin to correct this problem.

In addition, new regulatory provisions implementing Congressional mandates for improved integration and coordination of Medicare and Medicaid for dually eligible beneficiaries, require D-SNPs to coordinate access to and facilitate grievance and appeals for all Medicaid benefits for dually eligible members. This applies even to Medicaid benefits beyond any services D-SNPs may provide directly under arrangements with states. This provision makes it all the more important that there be mechanisms for easily sharing information between plan level payers as to which payer is responsible for services. Again, if done correctly, the new requirements for payer to payer data sharing could be helpful in implementing these new provisions.

Please also see related comments to the ONC rule, provided below beginning on page 22.

Recommendation 4. Enhance Daily State Submission of MMA Files with Additional Enrollment Information

The SNP Alliance supports the requirement that states submit daily MMA file updates identifying dual eligible beneficiary status as discussed in Section VII of the preamble. This will improve the timeliness and thus the accuracy of the MMA data that can facilitate new opportunities for default enrollment of newly dual members into eligible D-SNPs aligned with their Medicaid plan under state approved arrangements to promote additional integration. We also have the following future suggestions related to this provision.

Explore Adding Enrollment Information to MMA Files to Create a Single Source of Medicare Medicaid Enrollment Data for Dual Eligibles. We also recommend that CMS consider exploring utilization and expansion of this file submission for other related purposes. We understand that some states (such as Virginia) are sharing Medicare plan enrollment data from these files with their Medicaid plans while also providing batch inquiry data sharing mechanisms to D-SNPs on Medicaid plan enrollment. In response to the RFI for improving data exchange for dually eligible populations included in this section, we strongly recommend that CMS encourage or require all states to follow this process at minimum. But in addition, it is important that states and CMS understand and agree upon a source of data and consistent methodologies for tracking ongoing plan enrollments for both Medicare and Medicaid to facilitate care coordination and promote integrated programs. CMS could work with states to eventually add information about Medicaid plan enrollments to MMA files in order to provide an ongoing up to date source of Medicaid and Medicare plan information which might eventually be utilized to avoid misalignments in enrollment when conducting auto-assignments and to track integrated enrollment status for each plan and state to facilitate implementation of the new rule requirements.

Recommendation 5. Improving the Medicare-Medicaid Dually Eligible Experience RFI Response

CMS requests feedback as to how interoperability can be improved for federal state data for dually eligible beneficiaries. CMS has recommended some exclusions for other types of plans in this rule, but has not addressed special issues around MMPs, FIDE SNPs and LTSS plans, which are not currently equipped to meet these electronic interoperability standards and for which some of these provisions may not work as intended.

While FIDE-SNPs provide Medicare-covered services, many of the Medicaid-covered social and support services they and MLTSS plans arrange for occur in settings well outside of the scope of standard code sets and EHRs. And many LTSS providers that contract with FIDE-SNPs and MLTSS plans—wheelchair ramp installers, personal care attendants, Meals on Wheels programs—have little or no experience with the electronic records that would drive the interoperability sought by CMS in this proposed rule. Further, where these plans are integrated between Medicare and Medicaid, there are many operational issues related to data sharing that need to be worked out to avoid duplication and confusion such as joint vs separate provider directories, joint vs separate Medicare and Medicaid claims and clinical data submissions for which special use case scenarios should be developed and tested. CMS should extend deadlines further to redesign, test or pilot and phase in aspects of this interoperability rule for Medicare and Medicaid plans serving dually eligible individuals in these programs.

Proceeding with these interoperability rules without consideration of current integrated Medicare and Medicaid operations as well as new requirements for integration of both programs could further complicate or impose new barriers to integration, and at the least may result in exacerbating confusion for enrollees of both programs. On the other hand, as we have also noted, we see great potential for additional value in the payer to payer and other exchange aspects of this rule, assuming many of these issues can be worked out over time.

Therefore in addition to the recommendations for including Medicare and Medicaid plan enrollment data in the MMA files and USCDI elements as outlined in items 3 and 4 above, we recommend that CMS establish a special stakeholder workgroup to identify and map out these potential overlaps, conflicts and duplications and to develop a feasible work plan and timelines for implementing special interoperability modifications designed to consider and facilitate integration and build capacity to address the challenges raised here for plans and provider networks involved in serving high proportions of dually eligible individuals, including Medicaid MLTSS plans, MMPs, DSNPs, FIDE and HIDE SNPs.

Recommendation 6. Interoperability Rule Interface with Stars and Quality Management Systems

We recommend that CMS consider that Medicare Quality Management and Stars measurement (QMS), State Medicaid Managed Long Term Services and Supports measurement and some specific regulations for SNPs will need to recognize in some way the impact of these interoperability rules (or vice versa) — for example in sharing of data necessary for supporting quality metrics and quality improvement projects, requirements around health risk assessments and other LTSS assessments, SNP required models of care, SNP-specific measures with measure specifications around assessment, care coordination, and other elements of care. There are existing rules and quality measures which impact SNPs and Medicare Medicaid Plans (MMPs) which delineate the type, format, and specifications for data to be used to construct/report on measure results. Further, since the Medicare Stars quality measurement and management system regulations have now been codified, the formal process of proposed rule, comment, and final rule is required to modify any substantive aspect of these requirements. Therefore, the timeframe of any action affecting data collection, auditing, and sharing caused by these interoperability rules would have to take this into account. Minimally substantive changes require at least a 3 year process prior to implementation. This means that changes could not be accomplished earlier than 2022 if outlined and open for comment in 2019.

ADDITIONAL COMMENTS BY SECTION

The SNP Alliance provides further detailed comment related to all of these recommendations below.

Technical Standards Related to Interoperability (Section II.)

CMS proposes that a variety of data be made accessible to MA enrollees, Medicaid beneficiaries, CHIP enrollees, and enrollees in QHPs in FFEs, by requiring that MA organizations, Medicaid state agencies, all types of Medicaid managed care plans, CHIP agencies, CHIP managed care entities, and QHPs in FFEs, adopt and implement “openly published” (or simply “open”) APIs. CMS collaborated with ONC to align with and leverage relevant the API policies ONC has proposed to implement Cures Act requirements. A covered entity implementing an API must take reasonable steps to ensure an individual’s information is only disclosed as permitted or required by applicable law and must establish and maintain security of PHI data and functionalities of the API. However, HIPAA covered entities are not responsible under the HIPAA Rules for the security of PHI once it has been received by a third-party application chosen by an individual.

CMS proposes to adopt both (1) content and vocabulary standards for representing electronic health information and (2) technical standards for an API by which the electronic health information must be made available. CMS also cross references requirements in the ONC rule, to require use of the foundational Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard, several implementation specifications specific to FHIR, and complementary security and app registration protocols (OAuth 2.0 and OpenID Connect Core)

SNP Alliance Comments

Consider Existing Capacity of Covered Entities. The SNP Alliance appreciates and supports the long-term goals presented by this proposal. Specifically, we are excited about the potential for:

- The ability to generate and share in making an accurate and comprehensive longitudinal record available to each beneficiary across settings and over time;
- The streamlined and efficient sharing of important medical, behavioral health, and long-term services and supports information across providers and with the health plan all currently engaged in the care and support to the beneficiary;
- The stimulation and support to the individual beneficiary—to engage in care, be more educated and aware of options, treatment, support services, and other information important for their understanding in self-care and decision-making;

- Real-time, pertinent, and accurate information across a continuum of care/support providers to assist with effective care coordination; and
- Alignment, reduction of duplicity, and streamlining of quality measurement and measure reporting, with the opportunity to compare across populations and sub-population groups, and to identify meaningful measures/measurement related to key characteristics and goals of individuals and groups.

These aspirational goals are laudable. We support working toward them with proper preparation, resource and capacity-building, technical assistance and training, and education. The current state of the environment, however presents a clear picture of how far we have to go. Readiness by providers, states, and health plans is widely variable. For example, recent reports about existing HIE and EHR capability present a picture of an industry still very much in the early stages of readiness.

Costs of interface and connectivity remain a very big hurdle for providers, particularly smaller organizations and those in rural areas where resources may be more limited and legacy systems may not have the capability to support these additional requirements. For example, the EHR INTELLIGENCE newsletter reports that providers still face substantial information exchange barriers. A survey of providers in six states highlighted a multitude of technical, financial, and regulatory challenges, with the costs charged by vendors for connectivity and interface being one significant issue. Surveyed providers reported that EHR vendors charged from \$15,000 to \$70,000 for interfaces.

(<https://ehrintelligence.com/news/providers-still-facing-health-information-exchange-barriers>). In addition, in a survey of post-acute providers, nearly 65% of skilled nursing facilities reported using an EHR, but rates of health data exchange remained very low at 30%

(<https://ehrintelligence.com/news/cms-seeking-to-promote-ehr-adoption-in-post-acute-care>).

Furthermore, state capability and capacity varies widely. Information from the ONC (November, 2018) reviewing the CMS Innovator Accelerator Program and state actions provides important lessons learned as follows:

- States are at different stages of their payment and delivery system reform efforts and therefore technical assistance and requirements need to remain flexible
- States have variable data infrastructure to support the automation of needed health IT capabilities
- States have work to do to support value based payment and delivery reform including: modernization of EHR and HIE, and development of a strong quality measurement infrastructure to standardize and validate quality metrics
- There are four pillars which are needed to support the development and use of health information exchange where states can work through their Medicaid programs: (1) provider qualifications, (2) service definitions, (3) quality plans, and (4) reimbursement rates and methodologies

Use of the FHIR Standard. CMS is requiring the use of the HL7 FHIR standard which is relatively new. While we support the use of this basic standard, it is our understanding that few health IT developers have experience using this standard and that it is not yet in final form. We also expect it will be hard to find qualified resources for development and maintenance of the APIs, driving up the costs of this requirement. We are also concerned that many, many provider EHRs will not be capable of feeding data to health plans in a sufficient manner to meet the new FHIR standards without costly modifications. CMS should also clarify whether plans will be able to require their providers to utilize their APIs vs providers insisting upon using their own EHR patient portals. Further, it is not clear to the average reader which data might be available to consumers at the provider level through an API and which data is kept and available at a plan level, and how they all relate to the TEFCA arrangement, and how any data differences are reconciled. These are additional reason for CMS to delay the effective dates of this rule.

Protection of PHI and State Specific PHI Requirements: While the SNP Alliance supports the concept that plan members should have secure access to their PHI and the proposal for health plans to establish and maintain an API that will interface with third party applications chosen by members, we remain skeptical that PHI can be appropriately maintained and HIPAA protected through the open API process as proposed. Current available basic API technology does not include the significant cybersecurity and authentication features that health plans will need. Health plans will need to implement costly technological safeguards before starting to transmit PHI to third-parties via open APIs. We request that CMS modify their proposed implementation time frames to support the development and implementation of necessary safeguards.

We also recommend that CMS develop additional ‘rules of the road’ for APIs and for third party administrators involved in interfaces for consumer access. All of these entities should be subject to regulatory oversight for HIPAA compliance to protect PHI privacy, prohibition of sales or competitive use of the data they are handling, and receive oversight and scrutiny with penalties for violations. This could be accomplished through a certification process for the APIs and any third-party application administrators needed to interface with them. These administrators should be liable for the same protections.

At its webinar providing an overview of this rule CMS was asked a number of questions about data security under this proposal and while CMS provided broad statements about their commitment to maintaining data privacy, we were frankly disappointed at the lack of specificity of CMS responses as to how this system could proliferate opportunities for something to go wrong. Given the current climate of public reports of and consumer concern over data breaches and hacking of private data, as well as the propensity for software glitches in all kinds of software applications we believe implementation will be challenging with respect to keeping data private.

Therefore, we recommend that CMS conduct tests to provide additional assurance that all APIs will safeguard PHI and that CMS develop additional guidance and specifications including a certification process for all parties to assure that developers are capable of producing APIs and third party software that accommodates intricate policy differences across states in protection of PHI for behavioral health and substance abuse or other local requirements. This may include reducing or consolidating the number of API developers, plan APIs and third-party applications approved for use by consumers to connect to health plan APIs.

The SNP Alliance appreciates CMS’ interpretation that HIPAA covered entities are not responsible under the HIPAA Rules for the security of PHI once it has been received by a third-party application chosen by an individual, but we are also concerned about how these applications will handle the many state specific data privacy and data sharing restrictions that apply to certain services such as substance abuse and behavioral health services and diagnoses. The SNP Alliance recommends that CMS assure that third party consumer facing applications can accommodate such variations according to ONC requirements.

Need to Add Health Plan Enrollment Data to USCDI (US Core Data for Interoperability)

Exchanges: The SNP Alliance strongly recommends that the specified USCDI information requirements for data exchange between providers and payers and between payers be amended to include data elements and/or information related to a beneficiaries’ health plan enrollment, including the type of health plan payer (Medicaid, Medicare Advantage, freestanding PDP, D-SNP, ISNP and CSNP or other payers as identified by CMS) as well as an individual’s enrollment and disenrollment dates, all of which are essential to appropriate and accurate management, identification and transfer of member medical records over time, and is necessary information for enrollees as well as for compliance with HIPAA requirements. Additional modifications may be required based on health plan specific functionality

differences that should be explored with use case development applicable to health plans as recommended in these comments.

Patient Access Through APIs (Section III.)

CMS proposes new provisions that require MA organizations, state Medicaid FFS programs, Medicaid managed care plans and others to implement, test, and monitor an openly-published API that is accessible to third-party applications and developers. Information to be accessible through the open API would include: adjudicated claims and encounters (including cost); encounters with capitated providers; provider remittances; enrollee cost-sharing; and clinical data, including laboratory results (where available), information regarding provider directories and formularies available through the open API and basic information for enrollees on how to get covered benefits in the plan and to facilitate decision making about plan choice, providers, and benefits.

SNP Alliance Comments:

Encounter and Cost Sharing Data. The SNP Alliance requests that CMS make significant revisions in the requirement to share cost data for claims and cost sharing. CMS should prohibit the pricing of source data (medical record data, laboratory data, and claims data) exported electronically by providers or payers to the interoperability system, especially data that may be used to measure provider or payer performance. Electronic Health Information should NOT, for purposes of this rule, or for information blocking provisions, include proprietary negotiated provider fee schedules. Data that either includes or could reveal proprietary fee schedules should not be required to be shared or be used for information blocking purposes. Standards should be in place to prohibit providers or third-party administrators from using data collected and aggregated from consumer access to their records for competitive advantage to drive rates or for sales and potential marketing of competitive information.

In addition, there is the potential that requiring the disclosure of claims information that, in the aggregate, could be reverse engineered to determine provider payments or confidential provider contracting terms, could enable violations of antitrust rules and negatively impact competition.

Rather than be used as a tool for consumer engagement, we believe this information is much more likely to be used by providers, which tend to have substantial market power, to achieve more favorable reimbursement rates and thus drive increases in health care costs and premiums. In addition, there are already other mechanisms for determining consumer cost sharing and it is not clear how these processes will interact or be kept current enough to be instructive or useful to beneficiaries. These proposed processes require further harmonization with other existing processes to minimize beneficiary confusion, and ensure consistency with other related data sources, especially in light of the requirements to share adjudicated vs. paid claims.

We also request CMS seek further input on turnaround times for claims and encounters. There are many variations and steps in the processing of encounters that will complicate determination of at what point it is complete and what price is attached. This information will not be easily decipherable or meaningful to the consumer. The one-day standard as proposed in this rule is not feasible given current system configuration and the short turnaround times will reduce reliability and accuracy of data. We believe accommodating this time requirement will necessitate huge IT system changes and upgrades which would be unnecessary with a longer time frame, such as 5 days.

Clinical Data. As explained in earlier statements, clinical data should derive from the provider (as its originating source) to ensure that it is shared in an appropriate manner. Further, having standards that

apply to some organizations, but not others (such as laboratory information) is problematic. Clinical information made available from the providers is likely to be more accurate, complete, and timely than information a health plan may have, which may be limited in scope and collected for a specific and narrow purpose not useful to the patient's overall understanding of their health care. Additionally, other laws may limit direct access to lab results by individuals, as some believe their complexity may require professional provider interpretation or translation for a patient to understand how the test result impacts their health or treatment. Therefore, providers themselves should be the primary and ultimate source of clinical information provided to patients.

In addition, it is not clear how the API process as applicable to health plans in this rule will relate to data available directly from the provider through the Trusted Exchange Framework already being established. ONC, through its rule on Certified Electronic Health Record Technology (CEHRT) standards, will provide a very useful pathway for individuals to obtain this type of clinical information. At this point it appears the two processes could duplicate consumer access points without assurance that data is consistent between the two processes. We recommend that the TEFCA process be primary for access to clinical data by the consumer.

API Documentation. We recommend that CMS provide further clarification and guidance on how the plan's chosen API interfaces with multiple approved published consumer facing apps from which consumers may choose. Both CMS and the rule language state that a plan must have "an API". But CMS stresses that patients should be able to choose their third-party application and be able to go on line and access their data without special effort, also indicating that there will be multiple consumer facing apps for consumers to choose from. While we understand that all applications must meet certain consistent standards, the technicalities of how to ensure that the health plan's chosen API and the potentially multiple consumer facing technologies work together to both access and appropriately protect their data are not transparent. Further, we understand that it is not always clear who is responsible for developing and maintaining the software for such consumer third party applications from which portals they may be ultimately drawing information. Both sets of entities should be subject to a certification process.

Initial and Routine Testing and Denial of APIs. The SNP Alliance recommends that CMS implement pilots or conducts other testing mechanisms to identify gaps and assure that API standards are working properly and that they translate to a health plan payer vs provider environment. CMS may be able to apply lessons from the Blue Button process in a testing phase to identify modifications that are needed before further application to providers and payers. In addition, CMS should provide more information about the processes or standards health plans can leverage to evaluate the applications for health plan use or for the required ongoing monitoring of how their API connects to third party applications used by consumers.

Enrollee Education. CMS should not underestimate the challenges and costs involved the development and deployment of educational resources necessary to make these APIs accessible and useful to the wide variety of populations served through many health plans and providers subject to these requirements. SNPs in particular serve populations with disproportionate levels of frailty, disability, mental health conditions, cognitive impairment and SDOH needs along with low incomes, social isolation and a wide variety of cultural and language issues resulting in health literacy barriers. These populations will require more investment in special educational approaches tailored to their needs than the typical population in order to prevent or reduce confusion in accessing and making use of the API technology and in interpretation and assistance for meaningful use of the available data. CMS must assure that these requirements will not have the impact of penalizing plans or providers serving high needs populations in

terms of certain reporting requirements and costs. Such costs must also be considered in rate development.

Further, CMS should clarify what is meant by “without special effort” for the consumer. Implementation of this concept will need to balance ease of access by consumers with need to protect privacy of data which can be very difficult for consumers with high levels of disability and cognitive impairment such as populations served by SNPs. Will logins, passwords, and email or text messages which are typical privacy protections needed for access to an individual consumers’ information be seen as “special effort” or will they be incorporated into the application interface in a simple enough manner to retain accessibility and agree to privacy arrangements? How will these align with what is being proposed under the TEFCA standards? There also may be special issues related to the frail and disabled populations served by SNPs regarding privacy agreements. Negative consequences of data privacy breaches may fall more heavily on these groups if privacy agreements are too complex or buried in pages of hard to read information.

Access to Published Provider Directory Data (Section IV.)

CMS proposes to require MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to make standardized information about their provider networks available through API technology, so that third party software could access and publish that information. Such availability would be for current enrollees, prospective enrollees and possibly the general public to the extent existing regulations require that information to be disclosed beyond current enrollees. CMS proposes to require that the API technology conform to the API standards proposed by ONC for HHS adoption at 45 CFR 170.215 published on the same date.

SNP Alliance Comments:

Provider Responsibility and Standards for Accurate Updated Status. Both health plans and CMS must rely on accurate and updated information for provider changes in locations or employment. The SNP Alliance supports creating a uniform and standardized approach to enable machine readable provider directories which will benefit existing and potential members. However, in implementing these requirements, CMS needs to consider the current array of provider information reporting mechanisms that are mandated by the federal government, states or product lines (e.g. FFMs). The SNP Alliance recommends that these existing requirements be accounted for in this requirement to reduce provider burden and ultimately enable a more comprehensive and efficient standard for provider demographic and access information.

For example, the process needs to avoid resulting in conflicting and confusing information, e.g., where a member belongs to one plan for his/her Medicaid services (LTSS services or Medicaid companion services) and another plan for his/her Medicare acute and primary services. These two plans may be posting two different sets of information about the same provider. It is not clear how this is to be handled under this rule and CMS should consider providing additional guidance to address this issue to avoid confusion for consumers.

In addition, the payer may not have the latest provider information where the plan itself is a secondary depository of that information. Even with daily or weekly feeds, the network provider information posted by providers to plans is often already in error upon its arrival. To avoid this CMS could consider requiring providers themselves to post changes directly to the Trusted Information Exchange and that providers be held responsible for the accuracy and updating of their own information used in the Exchange and provided to all Exchange participants. Further, rather than having health plans negotiate such responsibility in their provider contracts for this and other interoperability data requirements, in the future, CMS should consider making such reporting requirements a fundamental condition of provider participation in Medicare.

Finally, while the SNP Alliance supports providing consumers with information on drug benefits, pharmacy directories, and formulary information, CMS must consider that policies may require rapid changes to formulary composition and pharmacy networks leaving them in flux and thus it may be difficult to simultaneously implement this provision with the other data requirements. CMS should delay this requirement until these issues are appropriately addressed.

Health Information Exchange and Care Coordination Across Payers: Establishing a Coordination of Care Transaction to Communicate Between Plans (Section V.)

Effective January 1, 2020, CMS proposes requirements for Medicare Advantage (MA) plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs to maintain a process to coordinate care between plans by exchanging, at a minimum, the USCDI at enrollee request at the specific times specified in the proposed regulation text. Plans subject to the requirement would, upon an enrollee's request: (1) accept the data set from another plan that had covered the enrollee within the previous 5 years; (2) send the data set at any time during an enrollee's enrollment and up to 5 years later, to another plan that currently covers the enrollee; and (3) send the data set at any time during enrollment or up to 5 years after enrollment has ended to a recipient identified by the enrollee. For dually eligible beneficiaries enrolled in MA plans and Medicaid managed care plans, both of the dual eligible individual's plans would be subject to the requirement to exchange that individual's data in the USCDI Version 1. CMS believes activities related to this proposal may qualify as a quality improvement activity for purposes of the Medical Loss Ratio (MLR).

Proposed SNP Alliance Comments:

Extension of Timelines. While we welcome the opportunity to streamline communications and share data between payers including data for dually eligible beneficiaries, the SNP Alliance believes the effective date of January 1, 2020 is entirely unrealistic for implementation of this provision. We recommend that CMS work with stakeholders to identify the specific capacity requirements, criteria, and technical capabilities that would signify a minimum level of readiness at a provider, plan, and state level. Furthermore, we recommend that resources to develop infrastructure, testing, and training be made available and that effective strategies be evaluated and disseminated so that organizations can learn from those out ahead. The infrastructure development, testing, and training should be fostered nationally. This is an important next step and a role that CMS can take on to encourage all stakeholders, including beneficiaries, be involved. The timeframe should be informed by a full environmental analysis.

USCDI Data Exchange. As stated earlier, we are aware of the lack of access to regular information for SNPs on the payer source for their members for key Medicaid services such as MLTSS (managed long term services and supports) and behavioral health services. This is especially a problem in states that have not chosen to or don't have the capacity to coordinate alignment of enrollment into the same plan for both Medicare and Medicaid. Thus, Medicaid MCOs are not sure of where their members are enrolled for Medicare benefits, and Medicare D-SNPs and other SNPs that serve large numbers of dually eligible members such as I-SNPs and certain C-SNPs, are not sure where their members are enrolled for Medicaid MLTSS and or behavioral health benefits. We also hear from states that they do not have an easily accessible source of data for knowing where their Medicaid beneficiaries are enrolled for Medicare, making coordination of care more difficult. We are hopeful that the new payer to payer data sharing requirement could begin to correct this problem.

Therefore we are concerned that the data sharing provisions required between payers under this rule as well as under the new related ONC rule (the USCDI data core data set) do not contain any mention of provision of health plan payer and enrollment source or enrollment and disenrollment dates, which are essential elements necessary for closer coordination of care between Medicare and Medicaid for this population as well as for sharing of health information between any payers as proposed. If this

information is implied somewhere in the process for the exchange mechanism, it should be expressly included in the rule, and if not implied, we strongly recommend that it be added to the core USCDI elements included in the USCDI exchange between health plan payers or otherwise explicitly provided with standardized requirements.

Specifically, for payer to payer exchanges, the SNP Alliance recommends inclusion of enrollment data such as plan identifiers, type and name, enrollment dates and disenrollment dates (when applicable) in the core data set. Initial review of the ONC proposed rule for updated USCDI data also does not appear to include this basic information, unless it is accommodated in some other manner behind the scenes. (See proposed ONC rule comment on a related section at the end of this document.) Inclusion of such enrollment data is essential to payer to payer communication for the coordination of care.

Gaps and Updates in Data. In addition, the requirement that payers/health plans provide and exchange 5 years of data history through the API methodology proposed will also be challenging. As recommended earlier, CMS should consider building on the TEFCA framework for the payer to payer exchange. CMS should note that not all providers are required to participate or will have data included or submitted to plans for various reasons (such as laboratory data), so source data at the plan level may be incomplete or inconsistent. Laboratory providers should be included in this rule. CMS should note that unless all providers are not participating in the scope of compliance for these requirements, or if data comes from second hand EHR sources, data may be conflicting and/or duplicative.

Dual eligible and Medicaid beneficiaries move in and out or are required to move in and out of health plan programs as circumstances change their status for Medicaid and MLTSS benefit status, institutional vs community residency, employment and relocation. CMS needs to provide additional specifications to clarify how these gaps apply to the requirement to provide five years of historical data.

It is also not clear how 5 year spans of data would be continuously updated or corrected for errors found and how patients would navigate multiple 5 year spans for the many different Medicare and Medicaid plans that might be available through the API over a 5 year period, or how the data for both Medicare and Medicaid would be coordinated. Further, if corrections are not made or carried forward, the information may be confusing or potentially harmful to patients. It will also be costly to warehouse such huge volumes of data.

USCDI Clinical Data Use Cases for Health Plans. We recommend that CMS re-consider whether the USCDI dataset (or which of its elements) are the most appropriate for meaningful payer to payer and health plan data sharing. In addition, CMS should build use cases specific to health plan operations that would support transfers needed for service authorizations and transitions as well as development of quality metrics, to ensure that standardized functions most essential to consumers are supported. CMS can incorporate what is learned from these health plan specific use cases to provide additional guidance for health plan data mapping requirements.

While we support the opportunity for health plan pathways for exchange of patient information, the SNP Alliance is concerned that the use cases upon which such data specifications are built may not be relevant to the manner in which health plans collect and maintain clinical data, leading to unintended consequences and confusion for beneficiaries. We anticipate that some data will be out of date, some data (such as lab results) may not be consistently reported or collected, clinical notes may be restricted for certain services, and some self-reported data may not be reliable (an important issue for SNPs, due to the larger proportions of beneficiaries with various cognitive impairments served by these plans.)

Further, it should be noted that some Medicare and some Medicaid plans support non-health care transactions such as home adaptations and that such additional types of such services are also now possible under Medicare supplemental benefits. These proposed USCDI standards do not appear to apply to these services, creating additional gaps in important information for care coordination that CMS may need to consider for future development.

Assessment Information: While exchange of assessment information between payers would generally be helpful to care coordination, especially the sharing of MLTSS and other assessment information between Medicare and Medicaid plans for dually eligible populations, CMS' assumption, as stated in the preamble, that this sharing and the use of a standardized data set will avoid the need for additional assessments is not correct for several reasons, including the need to meet additional and separate existing regulatory requirements. For example, there is a requirement in statute that SNPs must conduct a health risk assessments (HRAs) and submit a Model of Care (MOCs). HRAs are required upon initial enrollment with annual and periodic reassessments necessary for timely response to changes in health status. Models of Care have defined domains, factors, and elements pertaining to defining the special needs population, describing the care management and coordination processes, delineating the specialty provider network, team, and care planning, and pursuing specific quality initiatives. Models of care may also be required of plans by state statute.

CMS must also consider that Medicare and Medicaid assessment requirements often differ in purpose and timing (medical vs social or LTSS, initial, annual, specific service eligibility, change in condition, etc.), and across providers and plan types. Thus, one universal assessment will not be accepted or acceptable for all purposes. Medicaid statutes in different states may specify required elements which may differ from Medicare and from Star measure specifications. Each state sets its own contracting requirements for health plans. Sometimes a particular clinical discipline is required, that is, the skill base, education, and licensure requirements for assessors may be specified (e.g., physician/NP, RN, PHN, social worker). The location (physician office, in-home, in-facility) can also be specified. In addition, there may be specific state templates. All of this variety in state and federal statutory requirements around assessment, care coordination, and quality measurement reduces the likelihood that one standard set of required data elements will be sufficient and that simply requiring data exchange will reduce duplication. For all of these reasons, while we agree it may be helpful for payers and providers to share some elements of assessment data, CMS should avoid requiring a specific set of assessment data elements at this time.

Accommodation of State and Tribal Specific PHI Requirements. The SNP Alliance also underscores the earlier concern that there are specific state laws that govern privacy in specific use cases (such as for behavioral health and substance abuse information) and recommends that CMS provide additional testing and guidance for handling such cases and information between payers.

Care Coordination Through Trusted Exchange Networks: Trust Exchange Network Requirements for MA Plans, Medicaid Managed Care Plans, CHIP Managed Care Entities, and QHPs in the FFEs (Section VI)

CMS proposes to require MA plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs (excluding SADP issuers) to participate in trust networks in order to improve interoperability in these programs effective January 1, 2020.

SNP Alliance Comments:

As recommended earlier, we believe that CMS should build on the TEFCA provisions for the payer to payer exchange of health information, utilizing TEFCA as the single source for most available data (other than those data related to health plan functionality), and clarify how the TEFCA requirements impact the data flow from contracted providers to health plans and the payer to payer data sharing provisions in this

rule. CMS should revise the payer to payer rule sections to assure alignment and consistency with the proposed TEFCA standards and processes.

Improving the Medicare-Medicaid Dually Eligible Experience by Increasing the Frequency of Federal-State Data Exchanges (Section VII)

CMS proposes that states be required to begin participating in daily exchange of files currently submitted to CMS (called MMA files) which identify dually eligible individuals and are used for multiple purposes in both Medicare and Medicaid (including for Medicare buy-in data) with CMS by April 1, 2022 to support more timely access to coverage. CMS also seeks public comment through an embedded RFI on issues related to interoperability for services to dually eligible individuals.

SNP Alliance Comments:

Daily File Updates. The SNP Alliance supports the requirement that states submit daily MMA file updates identifying dual eligibles as discussed in Section VII of the preamble. This will improve the timeliness and thus the accuracy of the MMA data that can facilitate new opportunities for default enrollment of newly dual members into eligible D-SNPs aligned with their Medicaid plan under state approved arrangements to promote additional integration.

BBA Integration Standards. We also believe the proposal to require daily MMA files could be helpful for implementing BBA integration requirements including the data sharing with states and data exchanges on which Medicaid plan D-SNP members are enrolled (or vice versa) in order to facilitate the coordination of Medicaid benefits not provided through the D-SNP and the G&A assistance with Medicaid appeals under the new integration requirements for D-SNPs.

State Timeline Concerns. However, the SNP Alliance is also concerned that we have heard from states that the timelines for much of the proposed rule requirements pertaining to Medicaid are not feasible and that the effective dates (data files must be provided daily by April 1, 2022 and some of the other Medicaid provisions are effective July 1, 2020) are unrealistic.

RFI Responses for Improving Interoperability for Dually Eligible Individuals.

Stakeholders Group to Design Needed Modifications. Special needs health plans serve predominately beneficiaries who are dually eligible and receive a comprehensive set of services including primary, acute, behavioral/mental health, and long-term care. As such, SNPs and these beneficiaries are likely to be particularly impacted by these rule provisions. In response to the RFI questions, these rule provisions as proposed are not adequate for considerations related to these populations as already noted above in comments related to API TPA protections for PHI (especially for behavioral health and substance abuse, sharing of USCDI information between payers which lacks enrollment data and key non-acute health services provided by health plans such as behavioral and LTSS services, potential data duplications and interactions due to overlapping services and networks (such as provider directories) and need for additional access features and education of consumers around use of APIs.

CMS has recommended some exclusions for other types of plans in this rule, but has not addressed special issues around MMPs, FIDE SNPs and LTSS plans, which are not currently equipped to meet these electronic interoperability standards. While FIDE-SNPs provide Medicare-covered services, many of the Medicaid-covered social and support services they and MLTSS plans arrange for occur in settings well outside of the scope of standard code sets and EHRs. And many LTSS providers that contract with FIDE-SNPs and MLTSS plans—wheelchair ramp installers, personal care attendants, Meals on Wheels programs—have little or no experience with the electronic records that would drive the interoperability sought by CMS in this proposed rule.

Further, where these plans are integrated between Medicare and Medicaid, there are many operational issues related to data sharing that need to be worked out to avoid duplication and confusion such as joint vs separate provider directories, joint vs separate Medicare and Medicaid claims and clinical data submissions for which special use case scenarios should be developed and tested. CMS should extend deadlines further to redesign, test or pilot and phase in aspects of this interoperability rule for these programs. In addition, proceeding with these interoperability rules without consideration of new requirements for integration of Medicare and Medicaid could further complicate or impose new barriers to integration, and at the least could be extremely confusing for enrollees in these programs. On the other hand, as we have also noted, we see great potential for additional value in the payer to payer and other exchange aspects of this rule assuming many of these issues can be worked out over time.

Therefore we recommend that CMS establish a special stakeholder workgroup (with involvement of MMCO and other appropriate staff experts) to develop a feasible work plan and timelines for development including specialized use cases, testing and piloting and implementing specialized interoperability modifications designed to support and facilitate integration and to build capacity to address the challenges raised here for plans and provider networks involved in serving high proportions of dually eligible individuals, including Medicaid MLTSS plans, MMPs, DSNPs, FIDE and HIDE SNPs.

These special needs health plans and their specialty providers across a continuum of services, settings, and over time, may experience administrative and operational challenges more frequently and with more of the beneficiaries they serve—since these beneficiaries’ care and home support needs are frequently complex and multi-dimensional. Such administrative issues could include:

- Duplication or inaccuracy within data entry across multiple providers and systems, requiring frequent/constant accuracy and validation checks;
- Inconsistent or multiple definitions for a service or set of services with the same term, e.g. care management or care coordination, affecting the ability of the health plan to obtain and reconcile data within the measurement timeframe;
- Delay in timing of data entry relative to when service was received or delay in claims by providers resulting in incomplete information which invalidates or negatively impacts measure results; and
- Overlapping service periods or gaps in services which arise from reporting errors rather than delivery delays or duplication

In thinking about a full data exchange system with interoperability across the continuum, CMS must proactively prepare for and support such capacity building. This will be needed by providers, health plans, states, and at the consumer/public level.

Simply requiring data exchange through APIs will not reduce duplication or confusion. The harder task of alignment across states and in conjunction with disciplines, settings, service providers, consumers, and federal agencies –to understand and effectively set parameters on what data is needed and when, and by whom will be necessary. Without attention to reduction and streamlining of data elements the proliferation burden is likely to continue. This is sometimes referred to “just speeding up the mess.” The Agency for Healthcare Research and Quality has offered several key focus areas to guide stakeholders toward a robust system where there are clear expectations and accountabilities. They assert that policy and technology development must be linked and this requires an extensive commitment. Focus areas they identify as important include:

- Data use limitations
- Data ownership
- Governance
- Liability
- Anti-trust

- Roles and responsibilities of individuals and organizations

Expansion of Shared MMA Files for Tracking of Enrollment. With the new integration rule for D-SNPs and this RFI opportunity in mind, we also recommend that CMS consider exploring utilization and expansion of this file submission for other related purposes. We understand that some states (such as Virginia) are sharing Medicare plan enrollment data from these files with their Medicaid plans while also providing batch inquiry data sharing mechanisms to D-SNPs on Medicaid plan enrollment. In response to the RFI for improving data exchange for dually eligible populations included in this section, we strongly recommend that CMS encourage or require all states to follow this process at minimum. But, in addition, it is important that states and CMS understand and agree upon a source of data and consistent methodologies for tracking plan enrollment for both Medicare and Medicaid to facilitate care coordination and promote integrated programs. CMS could also work with states to eventually add information about Medicaid plan enrollments to MMA files in order to provide an ongoing up to date single two-way source of both Medicaid and Medicare plan information which might eventually be utilized to avoid misalignments in enrollment when conducting auto-assignments and to track integrated enrollment status for each plan and state to facilitate implementation of the new rule requirement.

Additional Standardized File Exchanges between States and CMS. CMS also asks for input on sharing data for demographic information, care coordination, COBA, provider networks and program integrity. At this point it is hard to envision how these proposed interoperability rules will avoid duplication of data, seamless protection of PHI and better coordination of information between Medicare and Medicaid unless the many issues we have noted can be addressed prior to implementation or without initial exclusion of these plans. However, with a clear plan based on the overall framework and modified for addressing these duplications and conflicts, we believe the payer to payer interoperability platform as well as the provider to payer platforms will eventually have great utility for improvement in all of these domains. Of course that will only happen if there is thoughtful attention to the special issues raised here and sufficient time to address them. Rushing this through will result in inaccurate data that could move interoperability for these purposes backwards.

There are already some promising models in use which may be instructive. CMS can look to a number of processes already in place such as how Minnesota Medicaid coordinates joint enrollments for DSNPs and also conducts eligibility verifications for them using existing available Medicare and Medicaid and SSA data and Info-Crossing functions and data for the FAI demos. If similar data is available in other states, CMS states and plans could jointly contract with or train and designate entities such as state enrollment brokers to manage similar processes to avoid duplication and assure timely updates of demographic information, dual eligibility and MLTSS status as well as provide clear sources of enrollment to providers, consumers and other health plans as needed.

Ultimately, we believe there are countless possibilities for improving available data for many joint uses if CMS Medicare and Medicaid, states and plans are incentivized or motivated and enabled to work together to create and share various data files, even starting by building on what is already available in states. As suggested above, CMS could design standardized templates for additional frequent file sharing through MMA file additions or development of or mergers of other files shared between CMS and states to provide one source of that particular information, such as provider enrollment. This information could either be fed to the payer to payer and plan to payer interoperability system and then to the consumer, or in some cases could be a source of that standardized information to be included in the TEFCA and eventually the APIs for consumers in order to create a single reliable source for that data.

Request for Information on Advancing Interoperability Across the Care Continuum (Section XI)
CMS imbeds an RFI soliciting comment on how HHS can more broadly incentivize the adoption of interoperable health IT systems and use of interoperable data across settings such as long-term and PAC,

behavioral health, and those settings serving individuals who are dually eligible for Medicare and Medicaid and/or receiving home and community-based services. This includes needed measure development and concepts and quality improvement efforts assessing interoperability and care coordination that address PAC, behavioral health, home and community-based services, and other provider settings including the domain of “service delivery and effectiveness” and the domain of “person-centered planning and coordination. CMS is also interested in comments on the applicability and feasibility of measure concepts for PAC, behavioral health, home and community-based services as well as how to standardize and make interoperable certain patient assessment information. CMS also seeks comment on appropriate timelines for such work.

SNP Alliance Comments:

Impact of Requirements on Stars, QMS and quality measurement under State Medicaid programs pertaining to Home and Community Based Services. CMS must consider that Medicare Stars measurement and Quality Management system regulations as well as other regulations for SNPs may be impacted by these proposed rules. Some Star measures require specific assessment and other data elements be tracked and reported. If these are not included in the interoperability/health exchange dataset, then additional collection and tracking of data in other non-HIE systems will have to be done—making for additional burden and confusion. Likewise, State Medicaid regulatory guidance around the content, process, and contracting requirements pertaining to Medicaid managed long-term services and supports (LTSS) components, such as mandated assessments and quality reporting, may also be affected.

While we see the potential for more streamlined data transfer, as well as opportunity for more timely, accurate, and comprehensive data to be transmitted to health plans, substantial capacity building will be required first. This pertains to infrastructure, health information technology upgrades, testing, and training. Moreover, the measure specifications, in terms of data sources, timing, and populations targeted may need to be modified for certain Medicare Stars or MLTSS measures.

In thinking about a full data exchange system with interoperability across the continuum, CMS must plan for and support capacity building. With regard to home and community based (HCBS), post-acute (PAC), and other managed long-term services and support (LTSS) providers--often critical to effective care coordination and care management--a real and important issue is whether all of the necessary entities could be part of this interoperability platform. This would be very important for dually-eligible individuals, as they often receive significant and important home services to support their independence and function in the community. Leaving them out would not achieve the goal of a longitudinal, comprehensive care record for the beneficiary, providers involved in coordinating and managing care, or the health plan.

There is considerable variation in infrastructure, resources, and capacity of many HCBS/MLTSS providers, so Federal and state agencies or other external funding and technical support organizations will need to invest considerably in these organizations to develop necessary capability and capacity. In their Report to Congress in 2018, MACPAC reported a study which identified factors that officials in five states noted as being important to consider in readiness review—these factors included ensuring that information technology systems were ready to store information on beneficiaries’ service plans, that they were able to accurately submit information to providers and state systems in a timely way, and that they were robust enough to support timely provider payments.

Quality measures within MLTSS used by States also vary in terms of the focus, types of data needed, and providers involved. Many community providers do not currently have the capacity to provide the kinds of data needed, or meet standards to ensure accuracy, timeliness, or privacy/confidentiality, A June 2018 report to Congress by MACPAC found that: “. . .even for states and plans experienced in using managed

care to deliver acute care, using managed care to deliver LTSS presents a new set of challenges. For example, because Medicaid is the nation’s primary payer for LTSS, the implementation of MLTSS presents a major change to the provider community who may not have experience contracting with managed care plans.”

The Medicare and Medicaid quality management systems espouse principles for good quality measurement including: validity, accuracy, utility, and feasibility. Furthermore, the resulting measure reporting must be meaningful for consumers and plans and provide information that is actionable toward quality improvement. Measures of quality must also be clear about context and attribution—that is, to whom/what provider or time segment do the reported data pertain to? For example, the current HCBS measures rely on having a context for what the individual (beneficiary) is referring to when he/she responds to the experience of care measures. Interpreting the person's response on satisfaction with “care manager” services, for example, relies on understanding what person/setting/service timeframe the beneficiary is referring to. Many dually eligible and special needs population beneficiaries have many types of "care managers" and service providers involved in their care and support. Without this context, attribution and accurate evaluation of performance is nearly impossible. Therefore, even once community providers are able to collect, validate, safeguard, and transmit data in a timely and consistent way, there will be additional work required around this issue of attribution—even with a fully operational health information exchange.

As this aspirational comprehensive data repository/platform is built and robust APIs established, there will need to be real-time information available—which extends across community-based services, clinics, hospitals, post-acute, behavioral health, and other long-term services and supports providers. When that is done and when the system can accurately identify an episode of care or care experience which is tied to a beneficiary's response in self-report surveys, then the system will be able to support aligned and meaningful quality measurement and reporting. It is a worthwhile goal. Such capability would allow payers and performance evaluation systems to appropriately assess an entity's performance and pinpoint success or opportunities for improvement. Providers’ performance could be factored in health plan decisions whether to continue to contract with providers or whether corrective action directives are appropriate.

However, unless these important infrastructure, capacity-building, measure specification changes, and quality reporting modifications are made, the resulting partial, incomplete, or inaccurate dataset might exacerbate currently problems or cause new ones.

As discussed, there are differences across states and between states and the federal government in statute around Medicaid and Medicare requirements that impact the type, content, format, aggregation, sharing, and reporting of data. These differences reduce the likelihood that one standard set of data elements will be sufficient to address all purposes. Simply requiring data exchange through APIs will not reduce duplication or confusion. The harder task of alignment across states and in conjunction with the federal requirements will be necessary. Without attention to reduction of data elements and streamlining of measurement and reporting, the proliferation of measurement and reporting burden is likely to continue. This is sometimes referred to “just speeding up the mess.”

Request for Information on Policies to Improve Patient Matching (Section XII)

Congress has limited CMS’ ability to require a unique identifier for each patient, therefore the safe and secure electronic exchange of health information is constrained as it is difficult to ensure that the relevant records are all for the same patient though HIPAA required the adoption of a “unique individual identifier for healthcare purposes,” commonly referred to as a UPI. However, CMS is not precluded from exploring improvements in patient identification and Congress has supported such actions, therefore CMS is soliciting comment on potential strategies for improving patient matching.

SNP Alliance Comments:

Patient matching technology is obviously necessary for sharing of information between providers and between payers including Medicare and Medicaid health plans. CMS should use this opportunity to develop a “source of truth for eligibility and demographics for dually eligible individuals, including Medicaid and Medicare plan enrollment, which would be more efficient for all parties. To the extent that such processes are being developed as part of the TEFCA standards, consistent elements could be applied to payer to payer data sharing for patient matching as well.

Respectfully,



Cheryl Phillips, M.D.
President and CEO, SNP Alliance

SNP ALLIANCE COMMENTS: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Submitted via Federal e-Rulemaking Portal: <http://www.regulations.gov>

May 24, 2019

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Office of the National Coordinator for Health Information Technology
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RE: RIN 0955-AA01: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Dr. Rucker:

The SNP Alliance is pleased to provide comments to CMS regarding the proposed rule implementing the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.

The SNP Alliance is a national, non-profit leadership association addressing the needs of high-risk and high-cost populations through specialized managed care. We represent over 390 special needs plans (SNPs) and Medicare-Medicaid demonstration plans (MMPs), with over 1.9 million enrolled members.

Our primary goals are to improve the quality of services and care outcomes for the complex populations served and to advance integration for those dually eligible for Medicare and Medicaid. Many of our member health plans have been leaders in the promotion of interoperability strategies. They are aware of the painstaking work required to develop and exchange health information across settings, services, providers, and payers, to improve the coordination and integration of care. Our comments are below:

Information Blocking (Section VIII.)

ONC's proposed rule details clearer prohibitions and permissions on actions that constitute information blocking actions. .

SNP Alliance Comments:

The SNP Alliance supports ONC efforts to define and inhibit information blocking actions. However, we request that it be made clear that the refusal to provide data access to an entity that intends to aggregate and commercialize other's data would be a legitimate reason to restrict access. We also suggest that ONC consider other forms of information blocking outside of IT based behaviors and that delayed posting of completed and validated data should not be accepted in this system,

Definition of Electronic Health Information (Section VIII.C.3)

ONC proposes to adopt an expansive definition of EHI that includes price and payment information.

SNP Alliance Comments

The SNP Alliance requests that ONC and CMS not include price and payment information in this definition. While we understand the need for additional price transparency for consumers, we do not believe the proposed system will ensure necessary protections against anticompetitive behaviors or will ensure that sensitive pricing data cannot be used and/or sold by the TPA for any commercial use or use that would not specifically benefit the member/patient. Even if not made available publicly, requiring the disclosure of price and payment information could be reverse engineered by TPAs to determine provider payments which is likely to encourage anticompetitive actions.

Updates to the 2015 Edition Certification Criteria (USCDI)

This rule proposes to use a standard set of health data classes and data elements (the USCDI Version 1 data set as updated) to support nationwide electronic health information exchange. In its interoperability rule, CMS also proposes that this data set be included in the APIs for patient use and for payer exchanges. (45 CFR 170.213-215.) HHS ONC and CMS both ask for comment on use of this data for the intended purposes.

SNP Alliance Comments:

The SNP Alliance is concerned that the specified USCDI information requirements for data exchange between providers and payers and between payers does not appear to include data elements and/or information related to a beneficiaries' health plan enrollment, including the type of health plan payer (Medicaid, Medicare Advantage, freestanding PDP, D-SNP, ISNP and CSNP or other payers as identified by CMS) as well as an individual's enrollment and disenrollment dates, all of which are essential to appropriate and accurate management, identification and transfer of member medical records over time, and is necessary information for enrollees as well as for compliance with HIPAA requirements.

HHS ONC should also not assume that providers maintain this payer information in an EHR system that feeds health plan level information, or that there is synchronization between provider level internal practice management systems (where this information may lie) and provider EHR systems. Therefore, it

is doubly important that the core data requirements include essential information about payers and the payers' sources of data which might include data from other payers over the 5 year period such data is to be collected and available to consumers and other payers as proposed in the related CMS interoperability rule.

We recommend that HHS ONC make necessary changes to require this information to be part of the core data set or clarify how this information can be included in the data exchanges including the TEFCA arrangements by other means. The lack of exchange of such information is also a continued barrier to further coordination of Medicare and Medicaid under new CMS regulations for D-SNPs which requires coordination of Medicare and Medicaid access to care and grievance and appeals across payers. Access to payer enrollment information between payers will be key to that process as well. The inclusion of enrollment information in the core data set require under this proposed rule as well as the proposed CMS interoperability rule will provide a unique opportunity to improve member's access to information as well as facilitate data exchanges between payers that can clarify data sources, reduce confusion and enhance care coordination.

We also recommend that HHS ONC and CMS consider whether the USCDI dataset (or which of its elements) are the most appropriate for meaningful payer to payer and health plan data sharing for interoperability purposes.

While we welcome the opportunity for improving payer and health plan pathways for exchange of patient information, the SNP Alliance is concerned that the use cases upon which the USCDI data specifications are built may not be relevant to the manner in which health plans collect and maintain clinical data, leading to unintended consequences and confusion for beneficiaries. We anticipate that some data will be out of date, some data (such as lab results) may not be consistently reported or collected, clinical notes may be restricted for certain services, and some self-reported data may not be reliable (an important issue for SNPs, due to the larger proportions of beneficiaries with various cognitive impairments served by these plans.) Therefore, we recommend that use cases specific to health plan operations be created, that would support transfers needed for service authorizations and transitions as well as future development of quality metrics, to ensure that standardized functions most essential to consumers and payers are supported.

Further, it should be noted that some Medicare and some Medicaid plans support non-health care transactions such as home adaptations and that such additional types of such services are also now possible under Medicare supplemental benefits. These proposed USCDI standards do not appear to apply to these services, creating additional gaps in important information for care coordination that should be considered for future development. What is learned from development of health plan specific use cases around such services can provide additional guidance for future changes reflecting the full range of important services provided to consumers.

Respectfully,



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