ACHP
ALLIANCE
OF COMMUNITY HEALTH PLANS

June 17, 2019

Submitted Via HealthIT.Gov

Donald Rucker, M.D.
U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201

RE: Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA), released on April 19, 2019

Dear Dr. Rucker,

Thank you for the opportunity to respond to the second draft of the Trusted Exchange Framework and Common Agreement that Congress directed ONC to develop under Section 4003 of the 21st Century Cures Act.

The Alliance of Community Health Plans (ACHP) is a national leadership organization bringing together innovative health plans and provider groups that are among America's best at delivering affordable, high-quality coverage and care. The non-profit, provider-aligned health plans that are ACHP members provide coverage and care in all lines of business for more than 22 million Americans across 34 states and the District of Columbia. ACHP members offer five of the fourteen 5-star rated Medicare Advantage (MA) plans. Overall, 34 MA contracts offered by ACHP members received at least 4-stars in the 2018 star ratings.

ACHP is commenting on the three complementary documents in the updated TEFCA draft:

1. The Trusted Exchange Framework, a set of principles by which health information networks should abide to enable data exchange.
2. The Minimum Required Terms and Conditions that Qualified Health Information Networks voluntarily agree to follow. The Minimum Required Terms and Conditions require:
    a. Support for a minimum set of exchange purposes for sending and receiving electronic health information, (e.g., Qualified Health Information Networks Targeted Query, Qualified Health Information Networks Broadcast Query, and Qualified Health Information Networks Message Delivery);
    b. Strong privacy and security protections for all entities that elect to participate, including non-HIPAA entities.

3. The Qualified Health Information Network Technical Framework, a document that details the technical and functional components for exchange among Qualified Health Information Networks.

The ONC will also award a private sector organization to be the Recognized Coordinating Entity that will have oversight, enforcement, and governance responsibilities for each of the Qualified Health Information Networks who voluntarily adopt the final TEFCA.

ACHP understands that this updated TEFCA package relates directly to health plan requirements in the proposed CMS and ONC patient access and interoperability rules. Accordingly, ACHP appreciates ONC's recognition in the new draft that there are several stakeholders involved, including payers, which must consider how to participate in a Qualified Health Information Networks to best serve consumers. It is important to ACHP member organizations that the TEFCA successfully engage various stakeholders' disparate information systems and recognize varying data needs to create a full and trustworthy patient health record.

Overall, we support ONC's effort to establish a network-of networks policy framework for trusted exchange of health information. ACHP members believe that the trusted exchange of health information through interoperable systems will improve care coordination, care management, and population health. Our members are actively seeking ways to create a more seamless exchange of information with health care providers so that they can better serve plan members and appreciate that this is also an objective of the latest TEFCA draft.

Generally, the TEFCA concept is new to health plans and, consequently, the industry requires more time to consider how to provide constructive feedback to develop a long-term, sustainable approach to nationwide data exchange. **At a minimum, ACHP requests that the Recognized Coordinating Entity to be selected by the ONC, work with stakeholders over time on new use cases and engage the payer community before beginning to operationalize the TEFCA.** It is important that the coordinating entity understand the different issues and concerns that payers have in participating in a Qualified Health Information Network before entering into agreements with Health Information Networks.

Specifically, ACHP believes there are several barriers to the successful implementation of TEFCA:

1. Uneven Health Information Exchange and Health Information Network Geographic Distribution and Sustainability.
2. Non-Transparent Governance Process.
3. Incomplete Privacy and Security Framework.

Uneven Health Information Exchange and Health Information Network Geographic Distribution and Sustainability

As ONC has previously reported, there are differing levels of engagement and operations among state and regional health information exchanges and networks. Currently health plans, including

ACHP members, participate in one, several, or none of these varying types of information exchanges, and have contrasting narratives about their experiences.

ACHP understands that the purpose of the TEFCA is, in part, to standardize Health Information Networks and create the possibility for participants to engage with only one Qualified Health Information Network rather than several. However, it is unclear how this would work for plans operating in multiple states. It is also unclear that there has been an in-depth discussion with regional, community and non-profit payers across the country that need assurances that implementing TEFCA will not interrupt existing Health Information Network / Health Information Exchange efforts. Where local level information exchange is working well, health plans need to know that their participation in a Qualified Health Information Network will be valuable, appropriate and address each region's needs. **ACHP requests that ONC study and report on the various experiences with Health Information Networks and Health Information Exchanges and build on those successes, particularly to ensure that the TEFCA does not prohibit existing innovative models to continue seamlessly on their current trajectory.**

ONC is also aware of the difficulties that health information exchanges face to remain economically sustainable over time. With a voluntary participation principle, and varying degrees of understanding and willingness to share data across competitor and multi-stakeholder entities, it is critical that ONC address more clearly the plan for economic sustainability of Qualified Health Information Networks. **ACHP requests that ONC host a series of roundtables with the health plan community and other stakeholders and issue a report based on those listening sessions that outlines a long-term plan for the financial stability that will support the goals of TEFCA. It is critical that these roundtables happen BEFORE the TEFCA is finalized.**

Non-Transparent Governance Structure

ACHP member organizations are concerned that the TEFCA structure, as proposed, will not meaningfully engage participants in policy, operational and technical decisions. In its proposed interoperability rule, CMS requires plans to participate in a Trusted Exchange Network, but ONC presents the TEFCA as a voluntary guidance document. In fact, participating in TEFCA is not a voluntary choice, at least according to CMS. We urge ONC to create an open participatory governance process and structure, including the creation of a TEFCA Oversight Board with balanced representation.

We are also concerned that the updated TEFCA is an overly complex and prescriptive set of rules over the entire Health Information Network / Health Information Exchange ecosystem. The new TEFCA appears to create barriers to organic innovation and collaboration with its top-down approach and lack of open and participatory governance.

Because of these more basic issues, ACHP declines to comment on the 15 specific inquiries in the new TEFCA. Instead, ACHP concurs with prior commenters that ONC should not specify particular standards or implementation mechanisms in the Common Agreement.

ACHP respectfully requests that the ONC and the Recognized Coordinating Entity work with private industry stakeholders to develop the technical framework and other parameters

that eliminate the prescriptive, burdensome required terms and conditions, and instead create guardrails for Health Information Exchange participants to operate in a manner that fosters competition, is flexible and promotes innovation. This is particularly necessary on items that lack industry solidarity, such as how to best identity proof and authenticate patient records, which are critical to the overall objectives of creating reliable and complete health care information.

Incomplete Privacy and Security Framework

As ACHP stated in its comment letters on the proposed interoperability rules, it is essential that we maintain public trust in the electronic exchange of health data as we modernize the system. ACHP member organizations agree that better access to information will help avoid mistakes and wasteful spending and otherwise improve the quality of care. Despite the obvious value in making information more available through Qualified Health Information Networks, there is a substantial level of concern about the privacy and security of this information.

We believe ONC should align TEFCA with HIPAA requirements and state laws, and work with the FTC to develop privacy oversight for non-HIPAA covered entities that participate in TEFCA. We are concerned that the TEFCA is establishing privacy and security requirements under contractually required terms and conditions that are above and beyond those defined by HIPAA and other federal and state laws, and are being applied to Qualified Health Information Networks, Participants and Participant Members, many of which are covered entities.

Indeed, modernizing information exchange and the growing number of relationships with non-HIPAA entities require a fresh analysis of privacy and security practices. Patient matching, authentication and identity proofing, and linking policy objectives with technical processes are known barriers to the functionality and secure exchange of electronic health information. ACHP appreciates that several of these issues are addressed by the draft TEFCA; however, health plans' particular issues – including immature data standards for interoperability and differing viewpoints on patient matching solutions – have yet to be addressed.

Finally, we note that the TEFCA encourages individuals to exercise a "Meaningful Choice" about whether to share their data. This appears to be an all or nothing action covering all personal health data exchange under the TEFCA. ACHP requests that ONC consider allowing a more nuanced approach than this blanket action, which may not allow individuals to distribute their own data in the manner and to the extent that they wish. The existing language may also cause confusion with existing federal and state data–sharing consent rules.

ACHP requests that TEFCA be implemented only at a time when these and other barriers to interoperability and privacy issues have been completely resolved and necessary guidance issued to the industry.

Conclusion

ACHP member organizations are proactively seeking ways to create a more seamless exchange of information with health care providers, public health agencies and other entities, so that we can better serve plan members. We appreciate federal agencies such as ONC issuing guidelines and general parameters for the operation of new health information exchange infrastructures that will advance this worthy goal. At the same time, we ask that the Administration avoid a highly-regulated, top-down approach to Health Information Networks and Health Information Exchanges that already exist and are working well. To accomplish this difficult work of "right-sizing" regulatory approaches to a complex system, we recommend that the ONC and CMS work with stakeholders directly to avoid reinventing a wheel where it is unnecessary and counterproductive to do so.

Thank you for the opportunity to comment on the TEFCA draft. We look forward to serving as a resource to ONC as we continue to focus on this important issue. At your availability, ACHP and its members would welcome the opportunity to meet with you and your staff, along with your colleagues at CMS, to further discuss operationalizing TEFCA implementation. If you have questions or require additional information, please contact Michael Bagel, ACHP's Director of Public Policy, at mbagel@achp.org.

Sincerely,

Ceci Connolly

Ceci Connolly
President and CEO
Alliance of Community Health Plans

ACHP
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OF COMMUNITY HEALTH PLANS

June 3, 2019

Donald Rucker, M.D.
Office of the National Coordinator for Health Information Technology
U.S. Department of Health & Human Services

Submitted electronically via www.regulations.gov

Re: [RIN 0955-AA01]: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Dr. Rucker,

ACHP appreciates the opportunity to comment on the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* proposed rule.

The Alliance of Community Health Plans (ACHP) is a national leadership organization bringing together innovative health plans and provider groups that are among America's best at delivering affordable, high-quality coverage and care. The non-profit, provider-aligned health plans that are ACHP members provide coverage and care in all lines of business for more than 21 million Americans across 34 states and the District of Columbia. ACHP members offer five of the fourteen 5-star rated Medicare Advantage (MA) plans. Overall, 34 MA contracts offered by ACHP members received at least 4-stars in the 2018 star ratings.

ACHP members support interoperable health care data exchange. Employing modern technology and transparent processes will enhance coordinated care, improve outcomes and reduce costs. These goals are aligned with our members' mission to improve the health system and health care for individuals and their families.

ACHP agrees with the proposed rule's purpose of providing patients with easy and immediate access to their medical information, but notes that this data is kept in electronic medical record systems by their clinicians. Health plans, on the other hand, receive only enough health care data to pay claims and perform other administrative tasks. Accordingly, the proposed rule's requirement that health plans must share clinical data with consumers is inappropriate at best, and at worst, could pose serious risk to patients who detrimentally rely on data that was not collected for medical purposes.

While the ACHP member organizations are generally supportive of the goals of the proposed rule, it is critical that ONC recognize the distinction between the minimal health data that payers possess and the comprehensive medical records maintained by clinicians. As detailed below, ACHP wants to make sure that reliable information is received at the right time by the right person from the right source, so that consumers can trust that the data they receive is actionable, private, and secure.

General Comments

Given our specialized membership, ACHP will not respond in full to the ONC proposed rule that is directed to non-health plan entities. There are a few provisions, however, that are incorporated by reference in the complementary CMS proposed rule on interoperability. There are other sections that we request either clarification or believe it is important to explain the impact ONC's proposed rule would have on community health plans. Accordingly, this comment letter covers three topics:

1. Technical standards that incorporated by reference in the CMS rule
2. Definitions of HIN and HIE
3. RFI on expanding the definition of Electronic Health Information (EHI) to include price information

Technical Standards of APIs

ONC's proposed rule refers to requiring the use of open Application Programming Interface (API) specifications and HL7 FHIR standards, which were engineered for clinical interoperability, not for information maintained by insurers. Instead, the payer community is familiar with HIPAA-named administrative transaction standards such as EDI transactions defined by ASC X12N. The rules further anticipate that the U.S. Core Data for Interoperability (USCDI) will be the basis for plan-to-plan data exchanges, a set of clinical data elements the provider community and its vendors – not health plans – have been focused on for the purposes of their EHR systems.

These long-term efforts to create provider interoperability standards are unlike the new initiatives underway for payers, most visible in the HL7-affiliated DaVinci Project. At the moment, there are no defined API enabled, FHIR-based standards for the four types of communication required under the proposed rule (plan to member; plan to plan; provider directory, and pharmacy/ formulary data). While work on these standards is underway, it will be some time before any are finalized, tested and mature for adoption and use.

ACHP requests that ONC work with CMS to determine exactly which API and FHIR standards are applicable to health plans. We further recommend that ONC clarify that only data classes and data elements for which the data provider is the source of the information should be required to be available for interoperable exchange. Specifically, clinical information should be sought from its provider-based source, not from payers.

Definitions of EHI, HIN and HIE

As part of its information blocking provisions, ONC proposes to define Electronic Health Information (EHI) as electronic protected health information (ePHI) and any other electronic information that:

- Identifies an individual or could reasonably be used to identify an individual
- Relates to the individual's health or condition
- Relates to the provision of healthcare to an individual
- Relates to the payment for the provision of healthcare to an individual

ONC requests comments on whether the definition of EHI should be the same as the definition of PHI under HIPAA. We strongly support the alignment of the two definitions. Aligning the two definitions will make sure that negotiated rate and price information will not be included. Further, if the definitions are identical, then the only difference is whether the information is in the hands of a covered entity under HIPAA (referred to PHI) or a non-HIPAA covered entity (referred to EHI).

Second, ONC also proposed defining a Health Information Network (HIN) as an entity that "enables, facilitates, or controls the movement of information between or among different individuals or entities that are unaffiliated." ACHP believes that this definition is too broad and could unintentionally include health plans. Current business practices that require confidentiality of communication may potentially become subject to data blocking provisions in which two entities may inadvertently form an HIN. Health plans, however, are not contemplated as being part of the information blocking provisions of the 21st Century Cures Act and should not be considered an HIN. ACHP requests that ONC clarify the definition to make clear that health plans are not included.

In another part of its information blocking provisions, ONC proposes to define a Health Information Exchange (HIE) as "an individual or entity that enables access, exchange, or use of EHI primarily between or among a particular class of individuals or entities or for a limited set of purposes." It is unclear how an HIE is distinguished from an HIN, and it is unclear whether health plans could be construed to be an enabler of the access to or exchange of EHI. ACHP recommends that ONC clarify the differences between the two terms (HIN and HIE) and provide examples of those differences. ACHP also requests ONC clarify in the final rule that health plans are not included in the definition of HIE.

RFI on Expanding the Definition of Electronic Health Information (EHI) to Include Price Information

ACHP supports providing consumers with price information to help them evaluate health care services and professionals to ensure they can make the most appropriate decisions at time of care. The definition of EHI, however, should be focused on health-related aspects of care and not cost information.

First, there are federal legislative proposals being contemplated to address the issue of surprise billing. ACHP encourages HHS to collaborate with Congress on a reasonable federal solution to the difficult problem of consumers being surprised by large and/or unreasonable provider charges, and refrain from attempting to resolve this problem via data regulation.

ACHP encourages HHS to work with Congress to better understand that surprise bills are generated by health care providers, not health plans, and are primarily the result of non-contracted providers balance-billing patients for emergency or unanticipated care not covered by the plan. Unfortunately, certain categories of physicians exploit the fact that consumers do not choose them but they are nevertheless necessary for some procedures. The classic example is an out-of-network anesthesiologist operating in an in-network hospital. These providers drive up costs by charging above-market rates. This issue can be resolved through the development of reasonable allowed charges and reimbursement criteria that is based on a range of usual and customary contracted rates and Medicare reimbursement in the same geographic region.

The solution is not forcing health plans and their contracted providers to reveal their negotiated prices that are created as part of complex and multi-layered agreements.

Second, access to price information alone is an inappropriate, insufficient way for consumers to evaluate the value of services and health care professionals. It is imperative that consumers are equipped with a full range of comparative data on value, quality, safety, effectiveness, convenience and price to make informed decisions about their care.

Keeping in mind that consumers should receive quality-related information along with price information, ACHP recommends the following list of data categories that may be most helpful to consumers:

- Out-of-pocket costs such as deductibles, copayments, and coinsurance
- Individualized cost estimates for pre-approved procedures, making clear the difference between a price estimate and a binding quote
- For non-risk-based arrangements, encounter data with de-identified aggregate price data, to help providers proactively manage care
- For risk-based relationships, claim and encounter information may be appropriate for individual consumers, and providers may need this information to participate in value-based care arrangements

Health plans already have existing processes for informing their members about coverage and cost-sharing prior to receiving care. In fact, several ACHP member companies are leaders in deploying personalized, real-time cost estimates to their members and continue to substantially invest in relevant, individualized price transparency beneficiary tools.

We recommend that providers be required to publish pricing data both by line item (e.g., billing code) and by bundled services. Alongside these data, health care facilities should publish the percentage of time when an out-of-network provider is used so that a patient can calculate the risk of receiving a "surprise" bill when using that facility.

Third, ACHP supports the use of FHIR-based standards for enabling payer price transparency. This information may be shared, where appropriate, before the services are delivered. An API exchange could facilitate such an approach for providers to request and display cost information from payers and/or practice management software to enable clinician and patient to engage in shared decision-making on necessary pharmaceutical, device or other treatment interventions. At the moment, there is no set of standards available for this level of price transparency.

ACHP requests that ONC work with CMS and the health plan industry to create the workflows necessary to support providers and payers that would appreciate these value-based relationships.

Conclusion

Thank you for considering our recommendations. We look forward to serving as a resource to the Office of the National Coordinator as we continue to address this important issue.

If you have questions or require additional information, please contact Tricia Brooks at tbrooks@achp.org.

Sincerely,

Ceci Connolly

Ceci Connolly
President and CEO

ACHP
ALLIANCE
OF COMMUNITY HEALTH PLANS

June 3, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS-9115-P
P.O. Box 8013
Baltimore, MD 21244-8016

Submitted via www.regulations.gov

RE: 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 (CMS-9115-P)

Dear Administrator Verma,

ACHP appreciates the opportunity to comment on the proposed rule to promote patient access to their electronic health information and interoperable health data exchange.

The Alliance of Community Health Plans (ACHP) is a national leadership organization bringing together innovative health plans and provider groups that are among America's best at delivering affordable, high-quality coverage and care. The non-profit, provider-aligned health plans that are ACHP members provide coverage and care in all lines of business for more than 21 million Americans across 34 states and the District of Columbia. ACHP members offer five of the fourteen 5-star rated Medicare Advantage (MA) plans. Overall, 34 MA contracts offered by ACHP members received at least 4-stars in the 2018 star ratings.

ACHP member organizations support interoperable health care data exchange. Employing modern technology and transparent processes will enhance coordinated care, improve health care outcomes, and reduce costs. These goals are aligned with our members' mission to improve the health system and health care for individuals and their families.

ACHP agrees with the proposed rule's purpose of providing patients with easy and immediate access to their medical information, but notes that this data is kept in electronic medical record systems by their clinicians. Health plans, on the other hand, receive only enough health care data to pay claims and perform other administrative tasks. Accordingly, the proposed rule's requirement that health plans must share clinical data with consumers is inappropriate at best, and at worst, could pose serious risk to patients who detrimentally rely on data that was not collected for medical purposes.

While the ACHP member organizations are generally supportive of the goals of the proposed rule, it is critical that CMS recognize the distinction between the minimal health data that payers possess and the comprehensive medical records maintained by clinicians. As detailed below, ACHP wants to make sure that reliable information is received at the right time by the right person from the right source, so that consumers can trust that the data they receive is actionable, private, and secure.

In summary, ACHP offers the following comments:

1. **ACHP supports the use of open APIs (application programming interface) for data sharing, but the technical standards required to implement the proposed rule are not ripe for adoption.** ACHP recommends that CMS issue an interim final rule to provide more time for feedback on the following suggestions. CMS should:

   a) identify the standards for APIs, align them with ONC's standards, and adopt implementation guides;
   b) provide greater clarity about the technical standards, allow for a staged implementation to consider the operational realities of these requirements and the further development of industry standards;
   c) explain how payer APIs will be measured, monitored, and enforced;
   d) invite plans to test standards and use cases for the purpose of developing an interoperability implementation process for the industry over the next several years; and
   e) provide federal grant funding opportunities and other support so that health plans may afford the necessary workforce and contractors to implement the scope of work envisioned by the rule.

2. **The scope of data that plans are being asked to provide is excessive.** To serve the goal of providing consumers with actionable and meaningful data, without creating unintended consequences, ACHP member plans request that CMS provide more guidance on how payers may offer the appropriate, minimum necessary information in response to an enrollee's request. Most importantly, health plans should not be asked to provide clinical data or proprietary contract information.

3. **ACHP member companies are unable to comply with the January 1, 2020 effective date in the proposed rule.** If all of the standards and implementation guides are ripe for adoption, health plans need at least 18 months from the publication date of a final rule to prepare and facilitate the budgetary, operational, technical and workflow changes necessary for compliance.

4. **ACHP is concerned about keeping health information private and secure under the proposed rules.** We request that CMS consider the following to increase the confidence of health care entities and consumers before requiring data transfers to unregulated third party applications:

a) Establish liability parameters;
b) Identify protocols that transfer liability and regulatory burden from one actor to another;
c) Identify best practices to hold non-HIPAA entities accountable for managing PHI;
d) Create a "white list" or other source of trusted app vendors that plans may safely rely upon.

5. **Conceptually, ACHP members agree that sharing plan information with other plans is important to coordinate our enrollees' health care, but there are operational considerations that must be addressed.**

6. **ACHP agrees that provider directory information should be made available to enrollees through an API, but there is disagreement on how to address poor data quality and other issues that must be settled first.**

7. **ACHP agrees that a Trusted Exchange Network concept will allow for broader interoperability, but descriptions of an exchange network need to be further defined.**

Finally, ACHP member plans offer their thoughts on the requests for information in the CMS proposed rule.

ACHP Comments and Recommendations on the Proposed Rule

PATIENT ACCESS THROUGH APIs

ACHP applauds the goal of making patient data available in a standardized format through an API so that third parties can offer applications that make the data available in an understandable, convenient and timely manner for enrollees.

We have several concerns with the proposed rule's implementation requirements:

A. the technical standards,
B. the scope of data,
C. the timeframes proposed, and
D. privacy.

1. Technical Standards

RECOMMENDATION: ACHP requests that CMS publish an interim final rule to further explore the standards and compliance provisions so these critical aspects of the rule will have the full benefit of the industry's experience and solutions. It is important to allow for ample time to consider the operational realities of these requirements, provide greater clarity about the rules, allow for the further development of industry standards, and provide for a public comment period as the full panoply of consequences becomes clearer over time.

OUR REASONING: Unlike health care providers who have had many years of experience with several stages of Meaningful Use of Electronic Health Records (EHRs) certification, APIs are a new concept to health plans. This marks the first time that every health plan in the country will have to work with – or even identify – IT vendors to implement an API platform to meet the proposed rule data access requirements.

The rule refers to API specifications that are aligned with HL7 FHIR standards, which were engineered for clinical interoperability, not for information maintained by insurers. Instead, the payer community is familiar with HIPAA-named administrative transaction standards such as EDI standards defined by ASC X12N. The rules further anticipate that the U.S. Core Data for Interoperability (USCDI) will be the basis for plan to plan data exchanges, a set of clinical data elements the provider community and its vendors – not health plans – have been focused on for the purposes of their EHR systems.

RECOMMENDATION: ACHP seeks greater clarity about the technical standards, and requests a staged implementation to consider both the operational realities of these requirements and for the further development of industry standards. ACHP requests that CMS invite plans to test standards and use cases for the purpose of developing an interoperability implementation process for the industry over the next several years.

OUR REASONING: ACHP supports the overall goal of identifying a set of base standards adopted by ONC for APIs and FHIR to improve information sharing among health care stakeholders. We applaud the Administration's efforts to steer the industry away from point-to-point data sharing solutions that tend to block information, frustrate the coordination of patient care and increase the cost of doing business. Standard APIs and FHIR-based applications will be a great opportunity for health plans to better engage enrollees for care management and allow a more transparent and collaborative process with providers.

Our members require greater clarity about the four sets of data exchanges called for in the proposed rule. Simply put, there is a lack of identified and available standards that have been finalized, tested and are mature for industry-wide use to provide these data sets to enrollees, health plans, providers and others.

While work on these standards is underway, it will be some time before any are ready for adoption and use. The new initiatives underway for payers, most visible in the HL7-affiliated DaVinci Project, are not yet complete or fully tested.

We recognize that the CARIN Alliance is working on two of the types of communications (health plan to member and pharmacy data), but we are unable to evaluate any results at this time. Indeed, CARIN is working on implementation guides to help the health plan industry share claims data with consumers using FHIR-based APIs, but it is unclear whether CMS and ONC are going to adopt or approve of these guides. Similarly, we understand that DaVinci is working on development of standard FHIR implementation guides to address plan to plan and provider directory data standards. These too are in early stages of development and we believe they will need to be finalized, tested and evaluated for industry-wide use before being adopted.

Even if efforts are underway to help bridge these significant standard development gaps, we are unable to forecast our plans' capabilities to implement them, assess how long it will take, or the resources required, to comply with the proposed rule.

RECOMMENDATION: ACHP supports the alignment of the technical standards between ONC and CMS and does not support a separate set of standards for health plans. We ask that CMS clearly identify the standards for APIs, align them with ONC's standards and adopt implementation guides.

OUR REASONING: Perhaps to address the lack of payer-available standards, CMS is referring plans to the API technical standards that ONC is proposing for adoption in its proposed rule for health care providers, IT developers and health information networks. ACHP member plans appreciate the willingness of CMS to provide flexibility, but we believe that it would be helpful if CMS identified the API specifications necessary to meet the data access requirements.

It is also clear that USCDI is not yet appropriate for health plans. CMS is proposing that plans be ready to receive and disclose USCDI information, including clinical data and financial data, but the USCDI does not yet include financial data – information that is typical in an Explanation of Benefits. CMS must also recognize that payers do not have all of the clinical data that is available to providers.

RECOMMENDATION: ACHP requests further explanation about how payer APIs will be measured, monitored and enforced.

OUR REASONING: As health plans are not required by CMS to submit their API technology to an ONC-like certification process, it is unclear how CMS would assess compliance with the rule's requirements. The rule is silent on enforcement or an audit procedure, creating uncertainty about health plans' responsibilities and ability to comply. It is unclear how payer APIs will be measured, monitored and enforced.

If these requirements are to be enforced as a condition of annual contract for MA plans, for instance, CMS should define the process to determine compliance, and a process for correcting actions before blocking a contract. ACHP member plans are concerned that patient care may be disrupted, so CMS might consider a monetary incentive or penalty, instead of an all-or-nothing condition of a contract.

ONC has certification standards specifying how vendors can charge for API calls to share such data, but health plans need to make considerable up-front investments to support the needed technical and semantic integration.

If there was more time, a mature solution built for multiple payer organizations could be developed that anticipated many typical plan internal and integration scenarios. Given that health plans do not widely use FHIR APIs, this is not possible in the short-term, but CMS could invite plans to test standards and use cases for the purpose of developing an interoperability implementation process for the industry over the next several years.

<u>RECOMMENDATION:</u> ACHP requests that CMS arrange for federal grant funding opportunities and other support so that health plans may afford the necessary workforce and contractors to implement the scope of work envisioned by the rule.

<u>OUR REASONING:</u> For payers, significant resources will be necessary to collect data from numerous sources and conform them into a data set that could supply an API. With multiple membership and claims data engines, the required data is typically spread across several different payer platforms, operational and analytic data stores, and multiple provider tracking systems. The technical integration tools required must be selected and licensed to provide HL7 and FHIR development support. It is unclear how many vendors are in a position to provide the necessary roadmaps to offer this support to the payer community.

Moreover, it is unusual for payers to have in-house IT staff experience with HL7 and FHIR. It will require several months to build the consulting resources and internal staff training to develop the necessary competency for an API project like the one anticipated by the rule.

Constructing these APIs is a non-trivial undertaking. The implementation roadmap appears to assume an ability to receive notifications and take responsibility for accepting, consuming and storing information pushed from external parties. This is an effort well beyond simply being capable of publishing internal data to interested parties.

Finally, it is clear that FHIR standards will evolve over time, creating a non-trivial lifecycle of investments for several years to maintain compliance.

Without a widely-available solution, ACHP member plans in particular are faced with an un-level playing field between the very large and well-capitalized health plans and smaller, community-based plans that cannot spread this capital investment across millions of enrollees. This is particularly important given the ACHP member plans' participation in the individual market with scarce competition. We want to continue to support our individual plan members, but this rule would create an additional burden on our non-profit, smaller health plans.

As a result, we believe that CMS' assessment of payers' initial and ongoing investment is too limited. More importantly, there are better ways to accomplish these policy goals than asking each individual plan to create multiple processes while spending significant resources to collect data from numerous data sources and conform them into a data set that could supply an API. Supporting the CARIN Alliance efforts for vetting standards, mapping, implementation guides and sponsoring a toolkit and offering technical assistance will be helpful, but making funds available to support smaller, community-based plans will be critical to successful implementation of interoperability standards. We respectfully request more time to offer solutions in collaboration with CMS officials.

2. Scope of Data

RECOMMENDATION: ACHP member plans request that CMS provide more guidance on how payers may offer the appropriate, minimum necessary information in response to an enrollee's request.

OUR REASONING: The scope of data that plans are being asked to provide is ill-defined, excessive for a consumer's needs, and is more likely to create unintended consequences than it is to provide actionable data for consumers. The "minimum necessary" standard regulates the use of PHI by covered entities and their business associates for purposes of treatment, payment and health care operations. There is no urgent need to exceed the minimum necessary threshold by expanding the definition of health information or by promoting access to a patient's full record, regardless of purpose.

The subject areas covered by the API-ready data requirements are broad in scope. At a minimum, plans are likely to be asked to provide information related to plan eligibility, evidence of benefits, pre-authorizations, subrogation, coordination of benefits and claims that have, or are undergoing a grievance and appeal process. Many of these areas are self-contained within specialized health plan systems and may require access to attachments – current infrastructure will need significant rationalization and investment to support some of these operations, particularly if plans are relying on external partners and solutions.

Health plans claims data systems operate according to HIPAA transaction standards, but this exchange of information between providers and plans is not comparable to an enrollee's request for information. Rather, claims data encompasses multiple data elements that are meaningless and unhelpful for consumers. Indeed, the data in a claims database is not designed to advance clinical care, so it is important to identify which elements within a claim – items that are part of an Explanation of Benefits, for example – should be provided to the consumer.

RECOMMENDATION: ACHP asks CMS to remove the requirement that clinical data be shared by health plans with third-party apps. Clinical information may be valuable for payer to payer communications for the purpose of care coordination, but asking payers to provide clinical information to consumers will result in unintended safety issues.

OUR REASONING: Asking health plans to provide clinical data to consumers is inappropriate for several reasons. As previously stated, payers' information systems are not designed to capture or maintain clinical data as a core purpose. Under HIPAA Minimum Necessary requirements, only the data that is minimally needed to support provider/health plan payment and operational functions are submitted by providers to plans (i.e., administrative purposes, quality reporting, risk adjustment and utilization management). Accordingly, clinical data is not originated or updated by payers as they are by providers and their EHR systems. There is potential for confusion and adverse health events if consumers are utilizing clinical data from health plans that could be dated, incomplete or outright wrong. People should rely on their health care providers for their medical history and details about their treatment regimen.

Indeed, CMS just issued a proposed rule for the inpatient rehabilitation facility prospective payment system for Fiscal Year 2020. One of the purposes of the rule is to reconcile a patient's medication list with a subsequent provider when that patient is discharged or transferred from a post-acute care setting. By proposing 22 standardized patient assessment data elements and seven social determinants of health data elements, the proposed rule will support better care continuity and coordination, clinical decision-making, early clinical intervention and better data exchange and interoperability between care settings. This is exactly the appropriate prism through which clinical data should be regulated, not through health plans.

Providing a "data dump" rather than a refined response to a data request carries with it a high risk of unintended consequences. For example, payer databases include contracted rates with providers and risk scores. Some of the data health plans collect and use on enrollees' behalf is proprietary. There are serious risks inherent in making this information and cost-sharing public because it may be reverse-engineered to determine proprietary contracted rates.

One of the data classes referenced in the CMS proposed rule to be made available by health plans is clinical laboratory information. This is another example of data that is not routinely collected and not maintained by health plans in their systems. While health plans do receive claims for clinical laboratory services, none of those claims contain the actual clinical laboratory results. Only a small fraction of actual laboratory data is collected by health plans, usually in non-structured ways.

ACHP members agree with sharing personal health information that is important to the consumer for their use, but we oppose sharing information that is meaningless to the consumer, could provide an unfair competitive advantage to others, or allow for inappropriate uses. Health plans need standards to follow to address the purpose of the information and prevent the release of data that could lead to bad or unintended outcomes.

3. Health Plans Require More Time to Assess and Implement the Rules

RECOMMENDATION: CMS should remove the January 1, 2020 effective date of the proposed rule and provide at least 18 months from the publication date of a final rule to allow plans to prepare and facilitate the budgetary, operational, technical and workflow changes necessary for compliance.

OUR REASONING: Smaller, nonprofit health plans are especially unable to meet the January 1, 2020 effective date in the proposed rule. If all of the standards and implementation guides are ripe for adoption, health plans need at least 18 months from the publication date of a final set of rules to orchestrate the entire data and systems flow process. Alternatively, CMS may align the implementation date with the ONC's timeframe for EHR implementation in 2022.

ACHP member plans need time to make changes to legacy systems, work with their vendors and plan for the monetary and human resource investments needed for compliance. In addition, more time is needed for standard organizations such as HL7 to complete work on defined standard and data content and for plans to implement these new standards. CMS may consider a phased-in timeline for open APIs starting in 2022, tying the phases to the development of standards.

<u>RECOMMENDATION:</u> CMS should develop appropriate and reasonable timeframes for various data categories (e.g., adjudicated and non-adjudicated claims, encounter data) rather than impose a strict one-business-day deadline.

<u>OUR REASONING:</u> CMS acknowledges that payers' ability to provide data within one business day will depend on providers and other plan partners submitting the data on a timely basis. Health plans need sufficient time to modify contracts and educate providers about these new timing considerations.

We recommend that CMS reference the current explanation of benefits (EOB) as the basis for defining the data structures and financial data elements that should be made available to beneficiaries via APIs. For formulary and drug benefit data, we recommend defining the specific, available elements in a detailed FHIR-based pharmacy benefit standard as an addition to USCDI.

The timeline for making these data available via API, i.e., within one day of claim adjudication/encounter receipt, is not operationally feasible. We strongly recommend a more realistic timeframe determined by industry consensus, so health plans might verify and validate requested information before uploading it to the API-accessible site.

<u>4. Privacy</u>

<u>RECOMMENDATION:</u> It is our belief that consumer privacy is paramount and extra care should be taken to increase the confidence of health care entities and consumers before requiring data transfers to unregulated third party applications. We recommend that CMS:

a) Establish liability parameters – Work with OCR and FTC to establish a safe harbor for covered entities releasing data to non-covered entities under this rule, and define clear parameters that address at what point plans cease to be liable for breaches and misuse of enrollee PHI after releasing it upon request;
b) Identify protocols that transfer liability and regulatory burden from one actor to another;
c) Identify a common set of industry best practices to hold non-HIPAA entities accountable for collecting, using, managing and storing PHI in conjunction with FTC;
d) Create a "white list" or other source of trusted app vendors that plans may safely rely on to relieve plans from the burden of vetting apps. Consider utilizing the experience

of CMS in its Blue Button 2.0 to identify, vet, validate, and list third party apps that have passed CMS' evaluation, as the basis for having health plans subject to these regulations accept those apps.

OUR REASONING: ACHP member companies are *very* concerned about the privacy of health information moving from a HIPAA environment to a non-HIPAA environment when information is disclosed to a third-party application. Third-party vendors working with healthcare provider organizations accounted for more than 20 percent of breaches in the healthcare sector last year, according to a CynergisTek **report**. Not only is there a risk of secondary misuse of data, including selling and re-disclosing, without consumer controls or protections, but it undermines the trust in covered entities that have no choice under the CMS proposed rule but to empower third parties that are not held to the same privacy and security standards. Moreover, it could lead to patient safety issues if data is mishandled.

When CMS is able to offer these assurances, then plans will have greater confidence that consumer information will be safe from bad actors. ACHP further requests that CMS explore an ombudsman process for ensuring the third party applications are behaving ethically and provide recourse for health plans, EHR vendors and/or care delivery organizations that have suspicions or concerns about the third parties that are requesting access to electronic health information.

RECOMMENDATION: CMS should engage all stakeholders, including all relevant federal agencies, in a consumer education effort to ensure that people understand the risks associated with using apps. The requirement on plans to inform their enrollees about apps, how to protect their data and how to complain to the OCR and FTC should apply to other industry stakeholders. CMS should issue additional guidance to address particular consumer-focused privacy and security issues.

OUR REASONING: Consumers must have enough information to make a well-informed decision about whether to trust a third-party app. Individuals should be able to grasp both the benefits and the risks of sharing information with entities not regulated under HIPAA.

Health plans should be able to obtain objective evidence of the scope of consumer authorization, i.e., clear description of which specific data types the consumer authorized a third-party app to access. We are also concerned about security risks to internal systems if third-party apps are able to introduce malware or perform other damaging actions in health plan systems.

Additionally the lack of robust regulation related to use of PHI (including sensitive data such as mental health, STIs, substance use disorder, reproductive health etc.) increases the likelihood of harm to patients when the app they use is not subject to HIPAA or other strict privacy and security controls. Recent examples of technology companies using data in ways consumers did not know about, expect, or authorize suggest PHI from trusted health care entities could be used in ways that ultimately harm consumers. New interoperability requirements should follow – not precede – regulation of all apps that receive PHI (not just a subset of those apps).

CMS must issue additional guidance about how to handle the following issues:

a) Information being made available meets the needs of individuals regardless of language or cultural issues.
b) All of the health information subject to the HIPAA right of access may not be transferable through the API. This is a complex concept and will need to be sufficiently understandable to individuals.
c) Many enrollees are children and have particular issues related to consent. All stakeholders will need to accommodate (and possibly refine/develop) rules for minor access and control over health information and educate members accordingly.

RECOMMENDATION: CMS should work with the ONC to include a more detailed definition of what would be considered "individual access" in the Trusted Exchange Framework and Common Agreement (TEFCA), and create a set of best practices or code of conduct that the FTC can rely on to enforce appropriate behavior for exchanging health information.

OUR REASONING: ACHP is concerned about the Common Agreement protections in TEFCA, which is closely related to the Trusted Exchange Network participation requirement. The language in the Common Agreement definition of "individual access" contemplates that consumer-controlled apps would not necessarily have to be Participants or End Users but could instead "connect to" a Participant or End User. It is difficult to understand how an entity "connects" to the framework without being at least an End User. There needs to be more clarity about how individuals can connect to the infrastructure without giving up their rights to control how information in a personal app is further disclosed.

In the proposed rule, CMS repeatedly states that when a non-HIPAA covered entity discloses an individual's confidential health information that is not consistent with the privacy notice and terms of use to which the individual agreed, the FTC has authority to investigate and take action against unfair or deceptive trade practices. ACHP members are concerned that there is no obvious set of best practices or code of conduct that the FTC can rely on to enforce appropriate behavior for exchanging health information. ACHP member plans appreciate the efforts of the CARIN Alliance on this issue.

5. Plan-to-Plan Coordinated Exchange

RECOMMENDATION: CMS should clarify plan-to-plan data standards and prohibit the exposure of proprietary information to competitors.

OUR REASONING: We agree that leveraging interoperability to facilitate care coordination will help reduce unnecessary care and give consumers greater access to a more comprehensive history of their medical care across settings. From a conceptual standpoint, we agree that sharing this information is important to facilitate enrollees' care.

Our member plans are concerned, however, that some of the information CMS anticipates being shared with other payers will be used against us for competitive reasons. Payers should not be required to expose proprietary information or trade secrets.

ACHP member plans are primarily concerned that CMS is asking plans to share an enrollee's information up to 5 years after disenrollment with a competitor health plan, and cumulative data if a plan has access to multiple years of health information for an enrollee, through the USCDI data set. First, the USCDI is primarily clinical data and health plans have very limited clinical data. While plans may have limited lab orders they do not have clinical notes or other treatment information that would meet the care coordination goals sought by CMS.

Second, plans would be forced to accept other plans' "bad data" without having any ability to parse out how it was misleading or contained partial information. Third, consumers frequently churn in and out of health plans and payers may be required to accept and share data for benefits they do not support and have no ability to incorporate into their data set.

We are further concerned, as has been noted earlier, with the fact that there is no finalized, tested and mature standard to achieve this plan-to-plan information exchange. Without having such standard identified and defined, health plans should not be required to pursue this exchange, as it would mean that each health plan would have to use their own set of data content and standard format for exchange.

6. API Access to Published Provider Directory Data

RECOMMENDATION: CMS should create a multi-stakeholder, public-private partnership to establish data exchange standards related to provider directories, devise a demonstration project or pilot program to develop best practices, and set an appropriate implementation date that allows for adequate testing.

OUR REASONING: ACHP applauds the effort to make provider directory information available to enrollees and prospective enrollees through an API. We agree that broad availability of provider directory data would allow for innovation in applications or other services that help consumers more easily compare provider networks.

We look forward to additional guidance that CMS intends to provide on best practices relevant to FHIR-conformant open APIs to help organizations subject to the requirements proposed in the rule making. At the moment, there is no industry agreement about how to address provider directory issues.

ACHP agrees that updating these directories will be challenging as data quality continues to be poor. There is inconsistent adherence to and enforcement of existing accuracy rules that makes the CMS National Plan and Provider Enumeration System data unreliable.

This may be a good opportunity for a demonstration project or pilot program to develop best practices and make sure all carriers are prepared to launch an API solution with common criteria for provider directories. CMS should explore how to assess the accurate interpretation of provider data and the best way to present that information to consumers.

7. Trusted Exchange Network

RECOMMENDATION: CMS should wait for TEFCA to be finalized before asking plans to participate and offer flexibility so plans may decide which approach best leverages existing trust networks and HINs.

OUR REASONING: ACHP agrees that a Trusted Exchange Network concept will allow for broader interoperability beyond one health system or point-to-point connections among payers, patients and providers. The preliminary descriptions of an exchange network need to be further defined. It appears that CMS is requiring plans to support new trading partner services for participants in the network, such as creating and managing accounts and connectivity of participating organizations. In addition, participating in a Trusted Exchange Network would require plans to provide operating costs to monitor and provide IT support – which means additional investment in new staff or outsourced contractors.

Leveraging existing trust networks is tricky because they are uneven in scope and geographic availability. There are a limited number of networks today, and there is a need to expand and integrate more plans and providers into these networks. There also needs to be recognition for the differing level of operations of each network. For instance, some networks do not support secure messaging or electronic querying – the third criterion required by CMS for a Trusted Exchange Network. For some plans, this may mean joining more than one network to meet all of CMS' criteria.

THOUGHTS ON RFIs

RFI: Advancing Interoperability Across the Care Continuum

Thank you for seeking input 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 post-acute care facilities, behavioral health and those settings serving individuals who are dually eligible for Medicare and Medicaid and/or receiving home and community-based services. We offer the following measure concepts that can address the assessment of interoperability in these settings.

ACHP's members are long-time proponents of value-based health care payment models. Evaluation of value must incorporate meaningful measurement of value for all stakeholders, and requires interoperability across provider settings. Without such interoperability, the measures necessary for evaluating and paying for value are not possible. Metrics that evaluate value will require collection of data elements from multiple settings for a single measure, as well as longitudinal measurement to assess outcomes over time.

Additionally, value-based payment has rightly brought increased emphasis among health plans on reducing waste. The most effective and patient-centered approaches to waste reduction must not only include elimination of care that is unnecessary and/or likely to produce harm, but also care that patients do not want. Therefore, measurement concepts for interoperability should include the presence of patient reported goals and preferences for care, upon both admission and discharge for each setting in which an individual receives care.

Tracking of patient reported outcomes, such as functional status, across time – and therefore across settings – would support critical value-based payment goals. Consistent collection and sharing of patient reported social needs as a vital sign will support care coordination and accuracy of information that is likely to change over time. Contribution of data to community level measures would support shared responsibility for improvement and would incentivize data sharing across care settings.

RFI: Advancing Interoperability in Innovative Models

Thank you for seeking comment on the principles promoting interoperability in innovative payment and service delivery models through the Innovation Center ("CMMI"). The exchange of information across a variety of non-traditional data sources supports the social determinants of health and quality measure development necessary for value-based payment. We agree that CMMI should pilot the exchange of information across a variety of non-traditional data sources, including patient access and sharing of their own data via APIs. We believe this is crucial to understanding the minimum necessary data required to achieve specific use cases, as well as to build capacity for data sharing among PACs and community-based organizations.

ACHP asks that CMS promote innovation and relevance of data by allowing for a range of data sources, rather than specifying a limited set. Every community and health care market has different contributing factors to the health status of its population, and the data needed to monitor, improve and pay for value will vary, accordingly.

RFI: Policies To Improve Patient Matching

Our member companies believe that patient matching is a critical component to the success of health care data sharing. Indeed, patient matching presents a significant barrier to data exchange and the usefulness of data that is successfully exchanged between entities.

There is no industry consensus on how to proceed. The discussions range from consideration of supporting a Universal Patient Identifier (UPI) to using biometrics, referential matching, machine learning, and a host of algorithms, in lieu of a UPI.

ACHP cannot make a recommendation at this time about how to proceed. Accordingly, CMS should consider creating a public-private initiative to solve the patient-matching dilemma.

RFI: Information Sharing Between Payers and Providers via APIs

ACHP believes that leveraging common APIs and standards to share health data between these entities is a meaningful way to ensure the entire marketplace is progressing at the same rate. We reiterate the concern about exposing proprietary information to our plans' competitive disadvantage. Without time for further clarification and analysis, we also note that exchanging data between payers and providers via APIs may pose challenges to integrated delivery systems. Responsibilities for collecting and updating certain data may be a shared responsibility across multiple organizations and it would be unclear "which side of the house" would be responsible for sharing and in what form.

Conclusion

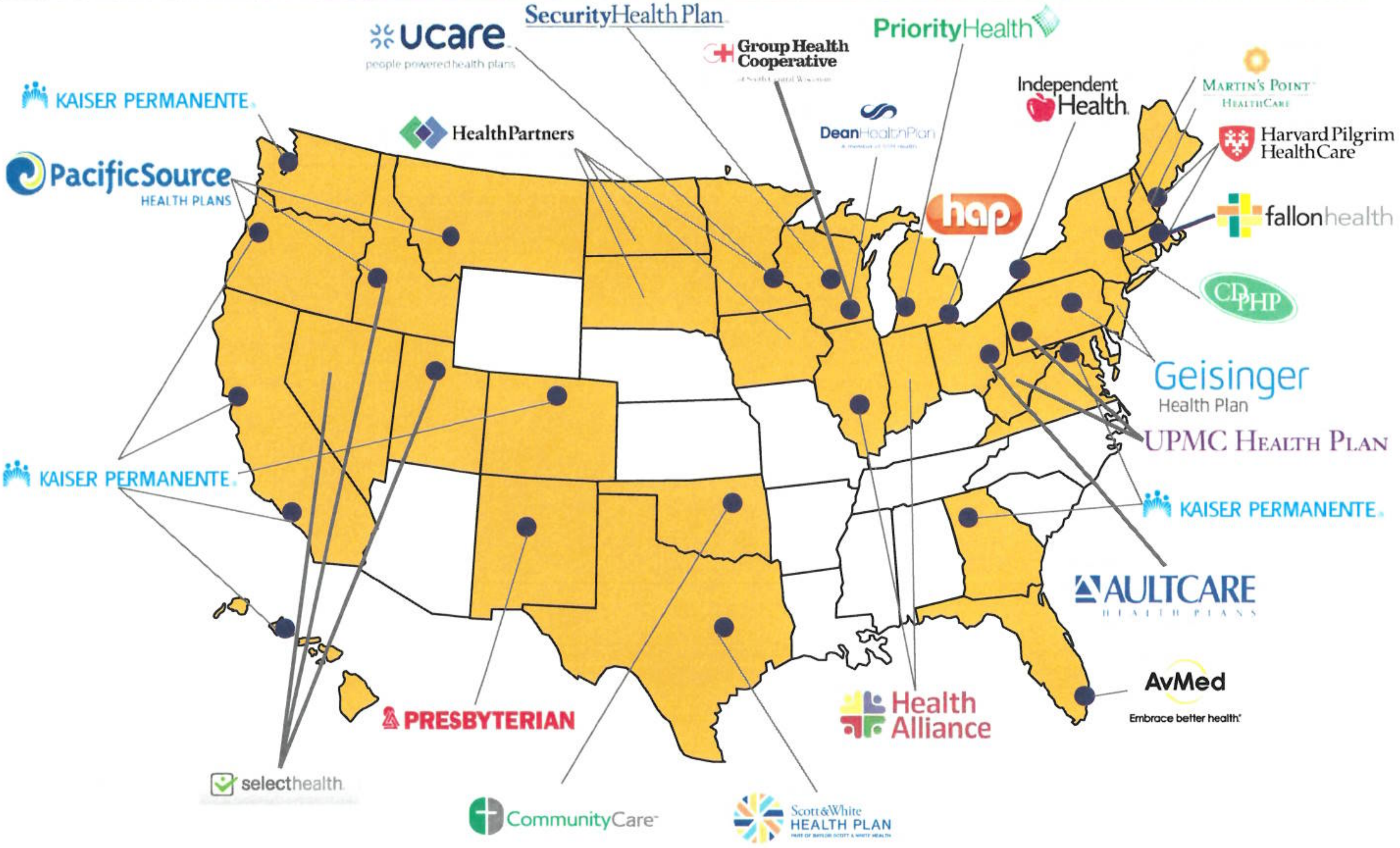
Thank you for consideration of ACHP's recommendations. If you have questions or require additional information, please contact Tricia Brooks at tbrooks@achp.org.

Sincerely,

Ceci Connolly

Ceci Connolly
President and CEO
Alliance of Community Health Plans

States with an ACHP Plan



02/01/2019

ACHP
ALLIANCE
OF COMMUNITY HEALTH PLANS

The Nonprofit Difference

Community health plans play a unique role in the American health care system. As nonprofit organizations, our mission is to improve the health of the communities we serve. Our member organizations are:

Driven by mission, not profit

As nonprofit plans, our members:

Don't answer to shareholders.

Focus on patients, not profit.

Reinvest in care delivery and the community.

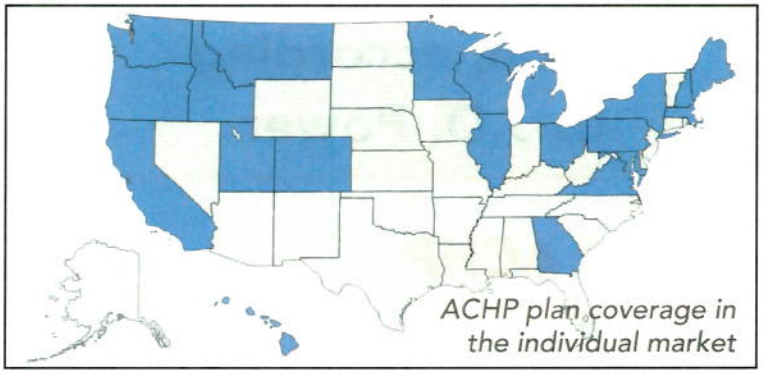
Our plans work with doctors and health systems to develop new payment models, improve outcomes and enhance care delivery, generating savings and better care.

Rooted in the communities we serve

On average, ACHP member plans have served their communities for

44 years

Our members are committed to serving the individual market, which is why ACHP plans have filled bare counties and most of our member plans continue to operate on the exchanges.



ACHP plan coverage in the individual market

By educating the public about opioids, providing mental health resources and offering free screenings, our members help improve the health of the entire community.

04.16.2019

ACHP
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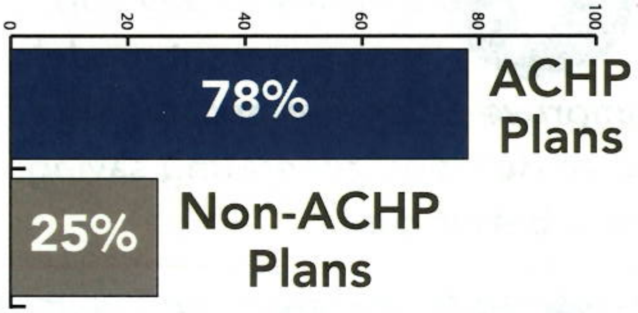
The Nonprofit Difference

Committed to high-quality, affordable coverage and care

78% of ACHP Medicare Advantage beneficiaries are enrolled in a 4.5 star plan or higher—compared to **29% of non-ACHP enrollees**

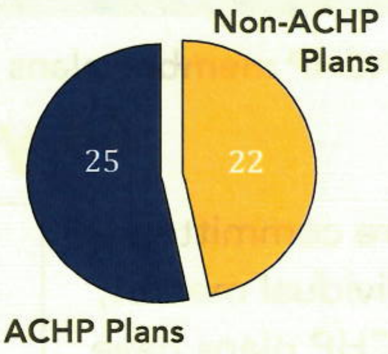


Average Medicare Advantage Star Ratings

ACHP Plans, 4.80 Stars

Non-ACHP Plans, 3.97 Stars

11 ACHP Plans are the top ranking plans in their region, according to J.D. Power



ACHP plans make up **more than half of all commercial plans** receiving an NCQA rating of 4.5 or higher

About ACHP

The Alliance of Community Health Plans is a national leadership organization representing nonprofit, community-based health plans and provider organizations. Our members provide coverage and care for more than 21 million Americans in 34 states and the District of Columbia.

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01.22.2019