Consumer-Purchaser
ALLIANCE
Better information. Better decisions. Better health care.

May 29, 2015

Andy Slavitt, MBA
Acting Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244

RE: Consumer-Purchaser Alliance comments on the proposed rule for the Medicare and Medicaid Electronic Health Record Incentive Programs – Stage 3

Dear Mr. Slavitt,

The 16 undersigned organizations representing consumer and purchaser interests appreciate the opportunity to comment on the proposed rule for Stage 3 of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs. The Consumer-Purchaser Alliance (C-P Alliance) is a collaboration of leading consumer, employer and labor groups working together to promote the use of performance measurement in health care to inform consumer choice, value-based purchasing, and payment.

The collective vision of the C-P Alliance is a future in which we have meaningful and useful measures of performance, including clinical and person-reported outcomes, coordination of care, affordability, and patient experience[1]. Such information can be used by consumers to make informed choices about their health care, by purchasers to shape the health benefits they offer, and by physicians, hospitals, and other health care providers to continuously improve the care they deliver. Critical to achieving this vision is a robust and effective health information infrastructure that streamlines the efficient collection, sharing, and use of health information by the full continuum of health system participants and stakeholders. True meaningful use of health information technology by an eligible health care provider includes making use of more available information and tools to improve patient experience and clinical care, to inform care coordination and communication with the full care team

[1] For brevity, we refer in various places in our comments to "patient" and "care," given that many federal programs and initiatives are rooted in the medical model. To some, these terms could imply a focus on episodes of illness and exclusive dependency on professionals. Any effort to improve patient and family engagement must include the use of terminology that also resonates with the numerous consumer perspectives not adequately reflected by medical model terminology. For example, people with disabilities frequently refer to themselves as "consumers" or merely "persons" (rather than patients). Similarly, the health care community uses the terminology "caregivers" and "care plans," while the independent living movement may refer to "peer support" and "integrated person-centered planning."

including the patient, to populate metrics demonstrating the value of care, and ultimately to improve health and quality of life.

We applaud CMS and ONC for recognizing that the meaning of health care providers as "Meaningful Users" of health IT must evolve with technology. The original concept that meaningful use would only apply to EHRs is outmoded, and the certification and incentive programs must adapt to include a wide array of health technologies and information users. The Stage 3 rule makes important steps toward a technology-agnostic model that focuses on function and outcome. We are pleased to see proposals for Stage 3 that enhance individuals' access to health information, that facilitate communication and information sharing with providers, and that meaningfully improve performance information about the health system. However, we have yet to fully realize the potential of health IT to support a high-value health system.

C-P Alliance appreciates the opportunity to provide input on advancements in the definition of meaningful use of health IT. As the program moves to a single, consolidated definition of meaningful use, we encourage CMS to use the opportunity to support a more comprehensive, person- and family-centered model of health care, and to ensure that the information infrastructure is truly used in a meaningful way to advance value throughout the health care system. We offer high-level feedback on Stage 3 and several of the proposed structural changes below, and more detailed comments on specific objectives and measures in the appendix.

Programmatic and Structural Changes

We support the proposed direction to move to a single set of objectives and measures to meet the definition of Meaningful Use, and applaud CMS for its efforts to simplify reporting requirements and reduce program complexity.

We acknowledge that CMS has modified the timeline for meeting the various stages of Meaningful Use in response to provider concerns about timely access to certified products. While we appreciate that CMS must be practical in operating a program that can be successfully implemented by the program's participants, consumers and purchasers are dismayed by the various delays in implementation of the Meaningful Use program because these delays keep critical information out of the hands of consumers and slow the pace of needed health system transformation. We strongly encourage CMS to move the EHR Incentive Programs forward as quickly as possible. In particular, we recommend that attainment of Stage 3 requirements remain mandatory in 2017 for any providers with two years of Stage 2 under their belts (i.e., any provider who first demonstrated Meaningful Use in 2011, 2012 or 2013) and make attainment of Stage 3 mandatory in 2018 for any provider who first demonstrated Meaningful Use in 2014 or later. We urge CMS to reconsider yet another year of delay that keeps important information out of the hands of consumers and purchasers.

We support the proposal to move from a 90-day reporting period to full-year reporting. This change makes the benefits of online access available to patients and families 365 days a year and requires the workflow changes to be implemented for a full year instead of a piecemeal approach to meeting the reporting needs. Full-year reporting periods are more likely to prompt changes in practice policies and provider workflows that are essential to realizing the full potential of health IT, and subsequently to transforming the delivery of

care and health outcomes. If a 90-day reporting period is finalized for any year or for first-time Meaningful Users, CMS should consider the downstream effect on measures with exclusions that were originally intended to apply to a full year of data, such as transitions of care and care coordination/engagement requirements.

We are encouraged to see CMS's response to concerns and recommendations from stakeholder associations and providers requesting changes to the Stage 3 requirements that would reduce the efficacy of the program. Though providers are a critical stakeholder, other stakeholders' needs must be met as well. The EHR Incentive Programs are one mechanism to address the important needs of consumers, purchasers, and others by encouraging improvements (not solely disruptions) to the clinical workflow, and by requiring the reporting of critical information to enable consumer choice, value-based purchasing, and care transformation such as shared decision-making. We agree with CMS that the recommendations to allow a provider to fail any two objectives, or to remove all measure thresholds, would substantially undermine the goals of the program. The proposed rule strikes an appropriate balance by incorporating flexibility to allow providers to choose measures most relevant to their practice setting and patient population among the public health reporting, health information exchange, and patient engagement through care coordination objectives.

Coordination of Care through Patient Engagement

We appreciate the close connections between patient engagement and care coordination – both are critical to high-quality health care systems. However, we are concerned that collapsing coordination and engagement measures may unintentionally undermine or dilute efforts to engage patients and families. For example, a provider could elect to send a secure message to another provider and/or receive information from a non-clinical setting (or a non-Meaningful Use eligible provider) – and meet the measures of this objective, all without truly engaging a single patient. We offer specific suggestions on the measures as proposed, as well as how to disentangle these two concepts (and associated measures) in the appendix.

We understand that application programming interfaces (APIs) offer significant promise with regard to new functionalities that support patient access and information exchange. We do have some concerns, however, about the wide-scale adoption and implementation of APIs, particularly with regard to level of function of APIs compared to existing mechanisms that support the view/download/transmit (VDT) functions. We encourage CMS to pursue the transition to APIs prudently, and require both the API option and VDT function for the time being. CMS should also clarify whether ONC-certified APIs will be publicly available, and affirm that there will be no barriers placed on consumers for use of APIs. We offer more specific recommendations with regard to patient electronic access in the appendix.

This proposed rule includes a number of important shifts that make the EHR Incentive Programs more patient-centered, including the clarification that patient-provider communication and patient information access can include patient-authorized representatives; the ability for patients and family caregivers to communicate electronically with providers; and the ability for patients to contribute information to their medical record that is specific and material to their care. We commend CMS for including these changes.

Clinical Quality Measures (CQMs)

We support CMS's previous work and current proposals to streamline the clinical quality measures used in various stages of the EHR Incentive Programs. In addition to reducing the burden of reporting different measures for different stages and different CMS programs, prioritizing a parsimonious set of high-value measures over a cacophony of checkbox measures, process measures, or topped-out measures also provides more useful information about the most important aspects of care quality and health outcomes. Currently, most electronic quality measures are retooled clinical process measures. The kinds of measures necessary to support new payment and delivery models are possible in an electronic environment, but systems and infrastructure must be designed accordingly. Electronic quality measurement should look across longer periods of time, utilize more data sources, and consider care in other settings beyond hospitals and ambulatory care such as long-term and post-acute care, behavioral health, palliative care, and community-based organizations, including those serving persons with disabilities. Technology developers must create and enable the functions and capabilities necessary for capturing information required to populate measures of patient engagement, care coordination, functional status, longitudinal (delta) measures, wellness and health promotion, and population-based measures that can be used to improve health, reduce disparities, and decrease costs. These measures must be available at many levels of granularity, such as individual clinicians, groups, ACOs, hospitals, integrated systems, and regions. Only then will we have the information we need to support new payment and delivery models and achieve better care, healthier people, and smarter spending.

We support the proposal to encourage clinical quality measure data submission through electronic submission for Medicare participants in 2017 and the mandatory electronic submission for these participants in 2018. We encourage CMS to move this timeline up as much as possible and would prefer to see mandatory electronic submission wherever feasible in 2017.

Thank you again for the opportunity to provide comment on the proposed rule for Stage 3 of the EHR Incentive Programs. The effective implementation and advancement of the Meaningful Use program and the streamlined Stage 3 requirements are critical in supporting needed system transformation to achieve the triple aim of better care, better health, and lower costs. If you have any questions, please contact either of the Consumer-Purchaser Alliance's co-chairs, Debra L. Ness, President of the National Partnership for Women & Families, or Bill Kramer, Executive Director for National Health Policy at the Pacific Business Group on Health.

Sincerely,

Organizations listed in alphabetical order
American Association on Health and Disability
Center for Patient Partnerships, University of Wisconsin—Madison
Consumers' CHECKBOOK/Center for the Study of Services
The Empowered Patient Coalition
Health Policy Corporation of Iowa
Iowa Health Buyer's Alliance
Lehigh Valley Business Coalition on Healthcare

Memphis Business Group on Health
Minnesota Health Action Group
National Business Coalition on Health
National Health Law Program
National Partnership for Women & Families
Pacific Business Group on Health
PULSE of America
St. Louis Area Business Health Coalition
Wyoming Business Coalition on Health

Appendix: Comments on Select Proposed Objectives and Measures

Objective 3: Clinical Decision Support (CDS)
Clinical decision support interventions are highly useful in improving patient safety and can improve the efficiency and value of health care. We support the proposal to retain both measures of the Stage 2 objective for Stage 3, particularly the continued link between CDS interventions and clinical quality measures (CQMs).

Measure 1: Implement five CDS interventions related to four or more CQMs
This measure has the potential to help providers improve the quality of care as well as their performance on CQMs. While the proposed measure offers a great deal of flexibility to providers to implement the interventions most relevant to their practice and their patient panel, we urge CMS to push further toward the highest value CQMs and require that at least one of the four CQMs chosen by the provider be an outcome measure.

In addition, we encourage CMS to consider opportunities to use CDS interventions to support person-centered care through the inclusion of patients' values, preferences, and goals of care, and shared decision-making.

We find it unlikely that any eligible professional, eligible hospital, or critical access hospital would be unable to select four CQMs related to their practice for this measure.

Objective 5: Patient Electronic Access to Health Information
As CMS notes, patients' electronic access to their own health information is a necessary function that supports robust patient-provider communications and enables person-centered care. However, we have some concerns about the proposed measures for this Stage 3 objective.

Measure 1: Patient Access to VDT or API
We applaud CMS for explicitly including patient-authorized representatives in this measure. Family members and other caregivers play a significant role on the care team, and due to their tremendous need for information about their loved one's care it is vital that they be included in strategies used by providers to meet this measure.

In general, we support the move toward API as a mechanism for consumers to access and use their electronic health information. This move has the potential to improve the user experience of accessing and sharing information for both providers and patients. However, we remain concerned about (1) the equivalent function of APIs compared to existing patient portals or personal health records, (2) the privacy and security of health information when using an API, and (3) patient-facing cost as a barrier to information access.

1. It is critical that an API used in lieu of the existing patient access mechanism (patient portal, personal health record, or other tool offered by the provider) maintain the same degree of information access. APIs must still offer patients the ability to view online, download, and transmit their health information within 24 hours of its availability to the provider, and to enable secure messaging and the capture of person-generated health data (PGHD). If an API provides some of these functions, a provider should continue providing the full complement of functionality through another mechanism.

2. We are concerned about the privacy and security implications for patients who choose to download their data (via a portal or API) and upload it into an app of their choice. These apps/devices may have poor privacy policies, weak security controls and/or policies that explicitly share data liberally with third parties or allow broad uses. Most apps are not under regulation by the Federal Trade Commission (FTC), Office of Civil Rights (OCR) or other federal authority. Additionally, many patients have limited knowledge and understanding of how privacy and security protections change (or end) when they move health data from a HIPAA-covered entity to a third-party app or device. We strongly encourage ONC, OCR and CMS to collaborate on ways to educate patients about their rights and steps they should take to protect their data, as well as to examine policy options that improve privacy and security for patients using these methods to access and use their data.
3. CMS notes that is has a preference for APIs to be available at no cost to the patient. However, we encourage CMS to clarify that any API used by a provider as a means for a patient or patient-authorized representative to access and use the individual's health information must be available at no cost to the patient. Just as there should be no charge for patients to use the VDT function, there should be none for using an API. Out-of-pocket costs should not prevent individuals from accessing and using their own health information.

In light of these concerns, we encourage CMS to require providers to continue to offer VDT, secure messaging, and PGHD capture functionality through existing patient portals or personal health records while also beginning to use APIs in the short term. We support proposed *Alternate A* (VDT & APIs) — to preserve existing electronic access and functionalities enabled through patient portals while APIs are tested. This will give the marketplace time to best meet the needs of both consumers and providers, understand both intended and unintended consequences of the shift to APIs, and to ensure continued availability of existing patient-facing functions. Functions such as secure messaging, online medication refills, appointment scheduling, etc. are part of many portals today, and allowing providers to discontinue these functions without a reasonable replacement may be highly disruptive for patients and families.

<u>Objective 6: Coordination of Care through Patient Engagement</u>
We appreciate the close connections between patient engagement and care coordination; however, an individual's engagement with her health information by itself constitutes neither patient engagement nor care coordination. We agree that making electronic health information available to individuals in a way that drives individuals to use that information can support effective care coordination and can further engage patients in care planning, goal setting, and shared decision-making. These activities are important and can result in better outcomes and decreased costs. The construction of this objective seems to conflate information use with both patient engagement and care coordination, and we recommend that these important concepts be treated—and incentivized—separately.

If the measures representing these concepts remain within a single objective, we recommend that providers meet the threshold for all the measures under the objective, not a subset.

Measure 1: Electronic Access to Health Information
We strongly support the requirement to document not only the offer of access but the use of online access. We are pleased to see the increased thresholds for both patients offered (80 percent) and using electronic access (25 percent). We applaud the advancement of this criterion toward real-time health information access and inclusive electronic health information exchange by accelerating the time frame for making information available to 24 hours. We support the second option to fulfill this measure using certified API as long as the API provides at least the full functionality to view, download, and transmit the individual's electronic health information and does not pose a financial barrier to access. Similarly, if APIs can meet this bar, we would support a clarification that a provider could meet this measure if 25 percent of unique patients accessed or used their electronic health information via either existing VDT mechanisms or API.

Measure 2: Secure Messaging
We support including authorized representatives as those who can send and receive secure messages to meet this measure. However, while it may improve the coordination of communication between a care team, solely copying a patient or an authorized representative on a secure message to another provider is not truly patient engagement. We recommend that such communications be counted in the numerator only with active participation or response, not simply viewing or being included in the communication.

Measure 3: Patient-Generated Health Data and Data from Non-Clinical Settings
Patient- or person-generated health data (PGHD) is an important and underused resource for improving care and targeting the health outcomes and issues most important to an individual. We are encouraged to see the inclusion of PGHD in this proposed rule and applaud CMS for identifying an opportunity to use a typically provider-centered program to advance the person-centeredness of care as well as building the data streams needed to evaluate true outcomes. We strongly support the capture of this information in a useful and structured way, and its inclusion in the EHR or other certified health IT module. In particular, we encourage CMS to incentivize the capture and integration of patient-reported outcomes over other PGHD, such as by weighting these data more heavily than other PGHD.

However, we are dismayed that the proposed measure conflates health information from providers not eligible for the Meaningful Use program (in this rule, referred to as "non-clinical settings") with PGHD. Both sources of information are important and both should be integrated into an individual's comprehensive health record in a useful and structured way that can inform further care plans and shared decision-making. The capture and integration of data from non-clinical settings reflect improved care coordination between members of the care team, defined to include those who are not eligible for the Meaningful Use program (e.g., nutritionists, physical therapists, psychologists, home health care providers). The inclusion of these data represents a different set of open communication channels than the capture of PGHD. We recommend that CMS separate the requirement to capture PGHD from the requirement to capture health information from non-clinical settings.

For both PGHD and data from non-clinical settings, we support retaining the provenance of the external data as part of the incorporation process. Retaining data provenance should be standard practice, and it is particularly important for incorporating PGHD. We also support including structured data elements for these data as fields in an EHR or other certified health IT module in as many cases as possible, particularly for PGHD elements most likely to

be captured by patients with multiple chronic conditions or other complex health conditions for whom self-monitoring is an important part of an ongoing care plan.

Objective 7: Health Information Exchange

We support the proposal to require that the summary of care documents used to fulfill this objective include the full Common Clinical Data Set (CCDS) specified by ONC in the 2015 Edition Certification proposed rule, and we request that CMS reiterate that the full CCDS must be included in any summary of care created or exchanged to meet this objective, not subject to provider discretion about clinical relevance. The CCDS includes demographic information, capture of which has been removed as a separate measure because of very high levels of performance (i.e., topped out).

We support the capture and inclusion of the unique device identifier (UDI) for implantable medical devices, and request that CMS clarify that documentation of the UDI must be done at the time of the procedure, not included post-hoc simply for a summary of care.

Objective 8: Public Health & Clinical Data Registry Reporting

Measure 5: Clinical Data Registries

In addition to their role in care management and quality improvement, clinical data registries can serve as a rich source of data for performance measures in accountability programs, such as public reporting and payment. To meet the needs of providers as well as consumers and purchasers, we recommend that clinical data registries included in this objective meet certain criteria. Our suggested criteria are:

Structural Criteria

- Governance by a multi-stakeholder board that includes meaningful representation by consumers and purchasers
- Demonstrated commitment to performance improvement, accountability, and public reporting
- In existence for a minimum number of years to establish viability
- Transparent as to purpose and sponsorship of registry, size and penetration, data handling capabilities, success with quality improvement, etc.
- Fees charged are reasonable and are used only to cover the costs of maintaining the registry

Data and Interoperability

- Data should be accurate and quality controls in place to ensure data integrity
- Registries should electronically interface with other data sources, including EHRs and other sources of data not included in the EHR (e.g., imaging, product bar code, other settings)
- Registries should also be able to transmit data electronically to third parties (e.g., vendors, CMS)
- Registries should use standards for common data elements, as they become available
- Denominator populations for registry-produced performance measures should include all relevant patients under the provider's care, whether publicly or privately insured

Measures and Uses

- Registries should have a commitment to performance improvement – not just to performance measurement – and should have a process for timely communication of results to support care management and improvement
- Reporting should be at the individual clinician and group level
- Numerators and denominators for accountability measures should be made publicly available to facilitate use in multiple programs (e.g., regional public reports)

While establishing criteria for clinical data registries that meet the terms of this measure may fall outside the scope of this rule, we encourage CMS to consider these criteria to ensure that reporting to a clinical data registry create not only an information channel but also useful information.