Mediphore Inc. Response to

Request for Information: Health Technology Ecosystem

CMS-0042-NC

Mediphore Inc.

Dr. Krishnamurthy Narayanan

CEO & Founder

nandu@mediphore.com

https://mediphore.com/

The Honorable Stephanie Carlton

Deputy Administrator & Chief of Staff

Office of the Administrator, Centers for Medicare & Medicaid Services

Department of Health and Human Services

7500 Security Boulevard

Baltimore, MD 21244-1850

Subject:

Response to Request for Information on the Health Technology Ecosystem (CMS-0042-NC)

Dear Deputy Administrator Carlton,

We are pleased to take this opportunity to submit our response to the Request for Information on the Health Technology Ecosystem (CMS-0042-NC) call by the Centers for Medicare & Medicaid Services (CMS).

The scope of the Request for Information on digital health solutions, with a strong emphasis on patient- and caregiver-centric perspectives additionally to providers' and payers' views, health data interoperability, accessibility, digital identity, and strengthening value-based care, aligns closely with Mediphore Inc.'s focus.

Below, please find our responses to specific sections of the RFI, clearly marked with the corresponding section identifiers. Additionally, more details and demonstration videos of our solutions can be found on our website at mediphore.com.

We look forward to working closely with CMS to bring digital health solutions to improve our nation's healthcare delivery.

Sincerely,

Krishnamurthy Narayanan

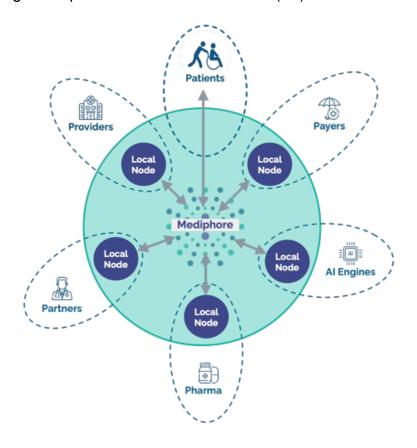
CEO & Founder

Mediphore aims for higher healthcare efficiency by re-engineering current medical processes, not just the data. Our proven and patented technology delivers solutions via an interoperable, non-disruptive, seamless, HIPAA & GDPR compliant platform.

Mediphore has developed and patented the System for Process Coordination and Interoperability Across Different Systems, Platforms, and/or Businesses (PIPCO) and the Intelligent Meta PACS system and server (IMPACS) to deliver medical images from one or more provider PACS systems to agents in the healthcare ecosystem including patients, providers, health systems, payer and insurance companies and others as authorized. With a central intelligence, processes and data sharing (including medical images, clinical and claims data) are simplified and optimized, ensuring operational savings and enhanced patient, provider and payer experiences.

The below architectural summary emphasizes our strategy to optimal handling of workflows and healthcare processes with seamless data sharing. Our architecture removes some of the challenges the current ecosystem has in place in USA healthcare.

Our current live system can scale securely with PCI/PII/HIPAA/GDPR compliant capabilities to millions of users horizontally and vertically. Please find a <u>link to our demo</u> videos highlighting the capabilities for all stakeholders (5P).



PC-1. What health management or care navigation apps would help you understand and manage your (or your loved ones) health needs, as well as the actions you should take?

- a. What are the top things you would like to be able to do for your or your loved ones' health that can be enabled by digital health products?
 - 1) Appointment scheduling
 - 2) Access to medical history & past appointments
 - 3) Easy to understand after visit summaries
 - 4) Access to medical records
 - 5) Access to doctor's notes
 - 6) View of current and past medications, easy to find info about my meds
 - 7) Lab results
 - 8) Messaging
 - 9) Access to tools that provide explanation of medical terms
- b. If you had a personal assistant to support your health needs, what are the top things you would ask them to help with?
 - 1) All the above
 - 2) + reminders for healthy lifestyles
 - 3) + suggestions, intelligent nudges

PC-2. Do you have easy access to your own and all your loved ones' health information in one location (for example, in a single patient portal or another software system)?

- a. If so, what are some examples of benefits it has provided?
 - 1) Yes, but since it is an Epic-based MyChart, its usability and the overall UX is questionable
 - 2) It has for our whole family all information in one place, but as kids are growing up, suddenly at age 12 and then at age 16 or 17 we parents cannot see anymore all information/details
 - 3) Even handling payments for kids over 12 years of age is not easy, as it just shows up as an invoice on my end but no explanation what the charge is for
 - 4) Overall, Epic's portal is far being delightful
- b. If not, in what contexts or for what workflows would it be most valuable to use one portal or system to access all such health information?
 - 1) See PC-1 answers

- c. Were there particular data types, such as x-rays or specific test results, that were unavailable? What are the obstacles to accessing your own or your loved ones' complete health information electronically and using it for managing health conditions or finding the best care (for example, limitations in functionality, user friendliness, or access to basic technology infrastructure)?
 - 1) In general, medical images are not available in my portal
 - 2) In many cases the overall medical history is not visible although we use the same provider for 15+ years
 - 3) Finding earlier visits to a particular provider within the same clinic is difficult to find
 - 4) Finding best care: this works typically by referral of our PCP, so not spending much on this aspect
 - 5) Biggest issue is price transparency: the clinic offers easy check in and shows some financial information, e.g. \$65 co-pay, but it does not disclose the usual price associated to a certain procedure, e.g. hearing test or minor surgical procedure. The surprise comes after the visit when the bill arrives with \$65 copay + some ridiculously high price
 - 6) Even when we call to insurance company beforehand, they want to know the CPT code and for that need to call back to the clinic, and that takes again lots of time, waiting, etc. Why not to disclose the CPT code before hand? If not known, at least a range of CPT codes for the potential procedure to be carried out. In case of a hearing test it is clear. In case of a minor surgical procedure things might change during the visit, depending what the surgeon discovers, yet, surely some range could be given with corresponding price points.

PC-3. Are you aware of health management, care navigation, or personal health record apps that would be useful to Medicare beneficiaries and their caregivers?

- 1) Yes, actually quite many.
- 2) However, my personal experience is that these apps promise far more than they are capable of.
- 3) Even they might be able to fetch my records, the outcome is unreadable, almost fully unstructured, no easy way to digest or even read. Not mentioning finding something within the records.

PC-4. What features are missing from apps you use or that you are aware of today?

a. What apps should exist but do not yet? Why do you believe they do not exist yet?

- 1) Medical image sharing apps —> this is actually what we at **Mediphore Inc.** provide
- 2) These apps do not exist because it is hard to make working smoothly.
- 3) Also, apps that would support a sort of "interpreter", that is explaining in plain language an after visit summary, certain medical terms, medication needs, etc. The rationale behind a doctor's thinking. This feature should work in a way that it works inside the app already used, sort of an invisible layer on the top of the medical record that interprets what said there in a plain language that. Layman can also understand.
- b. What set of workflows do you believe CMS is uniquely positioned to offer?
 - 4) Price transparency, pre-encounter information about pricing

PC-5. What can CMS and its partners do to encourage patient and caregiver interest in these digital health products?

- a. What role, if any, should CMS have in reviewing or approving digital health products on the basis of their efficacy, quality or impact or both on health outcomes (not approving in the sense of a coverage determination)? What criteria should be used if there is a review process?
 - 1) First, a user-based national panel should be set up that works in a codesign fashion with the administration. Any and all feedbacks this panel generates, the administration need to take into account and translate it to technical specification and user experience requirements
 - 2) The following measures are proposed:
 - i. **Efficacy**: every single app must have an objective it want to achieve. It must be clear from the start. If the app is not delivering on the initial promise, its efficacy is questionable.
 - ii. **Quality**: the patient experience must be smooth and seamless. The same terminology/wording/prompting must be used across apps, the same workflows must be implemented for user signup and verification
 - iii. **Impact**: measurable outcomes should be assessed, e.g. after-use questionnaires. Low scores must be re-evaluated and in cases the app does not serve the intended purpose must be terminated.
- b. What technology solutions, policy changes, or program design changes can increase patient and caregiver adoption of digital health products (for example,

enhancements to data access, reimbursement adjustments, or new beneficiary communications)?

- If the digital application offers timely responses, easy to use access to resources, questions are answered almost in real-time, the benefits will be very clear.
- c. What changes would enable timely access to high quality CMS and provider generated data on patients?
 - 1) The provider must offer the option for the patient to use certain digital apps
 - 2) It has to be made ready-to-use turn-key solutions, in the office visit signup etc. workflows must be conducted in no time
 - 3) It cannot work in that way that the elder patient goes home and tries to follow some instructions
 - 4) By the time gets home from the office visit, the app must be there and ready to use

PC-6. What features are most important to make digital health products accessible and easy to use for Medicare beneficiaries and caregivers, particularly those with limited prior experience using digital tools and services?

- 1) It is of paramount importance to design these apps with the patient in mind:
 - i. Large fonts to use
 - ii. Large buttons
 - iii. Minimum number of options
 - iv. Intelligent use of contextual information, e.g. filling up fields with known information about the patient Can be edited, but providing readily filled up makes a difference
- 2) Appointment scheduling
- 3) Messaging / communication
- 4) Interpretation of after visit summaries
- 5) Medication information, clear guidance of usage

PC-7. If CMS were to collect real-world data on digital health products' impact on health outcomes and related costs once they are released into the market, what would be the best means of doing so?

- 1) Tough to do
- 2) Basically Patient Reported Outcomes type of implementation needed, periodic inputs from the patient and caregivers

3) Best way would be connecting the dots in the background, e.g. after an appointment scheduled following up after the office visit done and medication picked up. Knowing all this, like an entire episode, the system could give a simple call or message offering to give a call and provide verbal feedback. That is easier than typing and answering questionnaires.

PC-8. In your experience, what health data is readily available and valuable to patients or their caregivers or both?

- a. What data is valuable, but hard for patients and caregivers, or app developers and other technical vendors, to access for appropriate and valuable use (for example, claims data, clinical data, encounter notes, operative reports, appointment schedules, prices)?
 - 1. Using Data Privacy as shield many apps are not able to use the clinical data to give an insightful information about the patient condition or medication. For example, currently apps that use the metric to help with lifestyle changes don't have the full clinical aspect of the patient to help them better. Instead, they only rely on the limited disclosure from the patient. We could possible give the data for such apps in a clinically accurate way to improve the usefulness while considering data privacy.
- b. What are specific sources, other than claims and clinical data, that would be of highest value, and why?
 - Normally lifestyle data such as sleeping patterns, eating habits, exercise routines, stress levels. Many of these are available from wearables. But we need secure way to integrate with the Clinical data for better health management.
 - 2. Any health, wellness and socioeconomic data, including, but not limited to Patient Reported Outcomes (PRO), patient generated and Remote Patient Monitoring (RPM) data, socioeconomic and Social Determinants of Health (SDoH), are essential together with clinical and claim data to give a better understanding of the individual, the whole person view of the patient.
- c. What specific opportunities and challenges exist to improve accessibility, interoperability and integration of clinical data from different sources to enable more meaningful clinical research and generation of actionable evidence?
 - 1. There is no easy framework to be able to integrate all this information using the standards such FHIR.
 - 2. These also don't account for advancements in technology. For example, if we need to incorporate voice based EMR record in FHIR its not easy.

PC-9. Given that the Blue Button 2.0 API only includes basic patient demographic, Medicare coverage, and claims data (Part A, B, D), what additional CMS data sources do developers view as most valuable for inclusion in the API to enable more useful digital products for patients and caretakers?

- a. What difficulties are there in accessing or utilizing these data sources today?
 - 1. No unified API for accessing data from remote monitoring, smartwatches, etc.
 - 2. Lacking standard for questionnaires that can collect PRO data.

PC-14. Regarding digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800-63-3 IAL2/AAL2 credentialing service providers (CSP)):

- a. What are the challenges today in getting patients/caregivers to sign up and use digital identity credentials?
 - 1. Identity provider services are fragmented. There is no nation-wide unified access to services due to lack of national-level identity provider.
 - 2. Take a look at the Scandinavian example: the identification of any person in the country is done via banking credentials. The assumption is that finance is a highly regulated area, a bank account can be opened only if a person is identified and it is typically done via an in-person meeting at the bank. Once the identity is established, credentials are provided, the account owner has means to access his/her account. In Scandinavia the very same so-called "strong identification" is used, except after the credentials verification the user is re-directed to the service that used the identification service. Whether that service is a government service, healthcare provider or system, or a college or DMV. See example.

PR-1. What can CMS and its partners do to encourage providers, including those in rural areas, to leverage approved (see description in PC-5) digital health products for their patients?

- a. What are the current obstacles?
- 1. Lack of knowledge, lack of choices and market.
- 2. Medical image sharing is lacking compared to sharing medical records. We at **Mediphore Inc.** definitely can help in this area.
- b. What information should providers share with patients when using digital products in the provision of their care?
- 1. Provider can play an essential role in assisting patients to sign up to the right tools. For many it might be hindering to do search, download, sign up, onboarding, etc. Providers' office could provide a kick-start for using

- these apps by automatically enrolling the patients and just simply demonstrating in less than 2 minutes how it works.
- c. What responsibilities do providers have when recommending use of a digital product by a patient?
- 1. They should have the same responsibility as prescribing medication. Digital products can be part of a digital therapeutic or digital medicine solution, thus the ultimate responsibility must lay with the provider.
- PR-2. What are obstacles that prevent development, deployment, or effective utilization of the most useful and innovative applications for physician workflows, such as quality measurement reporting, clinical documentation, and billing tasks? How could these obstacles be mitigated?
 - The issue is fragmentation and no-unified user experience. Every new app requires some level of learning and as these apps are coming from different sources, there is no concentrated effort to offer a unified experience.
- PR-9. How might CMS encourage providers to accept digital identity credentials (for example, CLEAR, ID.me, Login.gov) from patients and their partners instead of proprietary logins that need to be tracked for each provider relationship?
 - a. What would providers need help with to accelerate the transition to a single set of trusted digital identity credentials for the patient to keep track of, instead of one for each provider?
 - 1. Same answer as for PC-14
- PR-11. How could members of trust communities (for example, QHINs, participants and sub-participants in TEFCA, which requires Identity Assurance Level 2 (IAL2) via Credential Service Providers (CSPs)) better support the goals of reduced provider and patient burden while also enhancing identity management and security?
 - 1. In an ideal case one single-step identification would be sufficient, with that all QHIN offered services should be accessed and used.

TD-2. Regarding CMS Data, to stimulate developer interest—

- a. What additional data would be most valuable if made available through CMS APIs?
 - 1. Socioeconomic data, SDoH.

TD-12. Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?

 Considering that for value-based care and for whole-person treatment data beyond clinical information is also needed, included SDoH, PRO, wellness, etc. data, one can imagine that over time various data aggregators will emerge that might offer access to individuals' various types of data, like the ones above. In such cases a bridge solution is needed, like the one for Commonweal and CareQuality.

VB-1. What incentives could encourage alternative payment methods (APMs) such as accountable care organizations (ACOs) or participants in Medicare Shared Savings Program (MSSP) to leverage digital health management and care navigation products more often and more effectively with their patients?

 Patients should get the incentives based on the data they provide, wellness, PRO, medication adherence, participating to preventive offers, etc. back to their providers. Based on the regularity and amount of data patients, and based on that also providers, should be rewarded with discounts and other incentives.