belle.ai
precision skin health™

June 16, 2025

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy/National Coordinator
Department of Health and Human Services

Submitted electronically

Re: Comments on CMS Request for Information: Health Technology Ecosystem (CMS-0042-NC)

Dear Administrator Oz and Assistant Secretary Keane:

BelleTorus Corporation ("Belle.ai") appreciates the opportunity to provide input to the Centers for Medicare & Medicaid Services (CMS) on this important issue. Belle.ai develops dermatological artificial intelligence technology to assist healthcare providers in visually identifying, describing, and tracking skin conditions. Our flagship product, Belle 1K™ AI, is a smartphone-based application that uses geometric image analysis to identify and provide reference comparisons for more than 1,600 skin conditions. For patients with previously diagnosed immune-mediated skin disorders (e.g., psoriasis, eczema, alopecia areata, vitiligo), the Belle AI technologies offer additional quantitative modules that provide objective severity scoring to support longitudinal tracking by healthcare providers.

Belle.ai's tools are currently used by primary care physicians, dermatologists, public health agencies, and life sciences companies. Clinical studies are underway at several large U.S. healthcare systems to evaluate the utility of Belle in clinical settings. Furthermore, CMS invited Belle.ai to present at its inaugural Artificial Intelligence Demo Day in November 2024.

Following is our response to question PR-3: **How important is it for healthcare delivery and interoperability in urban and rural areas that all data in an EHR system be accessible for exchange, regardless of storage format (e.g., scanned documents, faxed records, lab results, free text notes, structured data fields)?**

We believe that comprehensive and interoperable access to EHR data is essential to improving patient reported outcomes and care delivery, especially in settings where dermatologic expertise is not readily available. This includes rural health clinics, Federally Qualified Health Centers, urgent care centers, and emergency departments.

For example, dermatologic conditions account for at least 5 million emergency department visits annually, (JAMA Dermatology, https://jamanetwork.com/journals/jamadermatology/fullarticle/426425). Yet most emergency departments do not have immediate access to a dermatologist. When clinicians are confronted with an unfamiliar skin condition, they typically must consult a specialist, resulting in delays and care bottlenecks.

belle.ai
precision skin health

The increasing number of medications in use has also led to a rise in dermatologic adverse drug reactions—now estimated to affect up to 10% of hospitalized patients and 1–3% of multi-medicated individuals (British Journal of Clinical Pharmacology; https://pubmed.ncbi.nlm.nih.gov/35974692/). The skin is the most commonly affected organ in drug reactions, making rapid identification and review of a patient's medication history critically important.

However, accurate medication reconciliation remains a persistent challenge. One study found that only 36% of patients correctly list all current medications on intake forms (https://pubmed.ncbi.nlm.nih.gov/21855261/). This gap could be significantly reduced by enabling point-of-care access to the patient's full, structured medication data from the EHR—data that could then be analyzed by software such as Belle to highlight known dermatologic adverse reactions for the treating clinician's consideration.

Today, interoperability challenges persist. While some leading EHR vendors offer test environments (e.g., FHIR-based sandboxes), these do not always reflect the full complexity or constraints of production systems. Integration with both vendor- and provider-operated EHRs typically requires custom solutions and ongoing coordination.

We strongly support CMS efforts to advance full interoperability across all data types and formats in EHR systems. Doing so would enable health innovation and improve patient safety, particularly in under-resourced settings. For technology innovators like Belle.ai, seamless access to EHR systems would accelerate our ability to offer solutions that improve public health.

Thank you for the opportunity to provide comments. Belle.ai welcomes further dialogue and collaboration with CMS and other stakeholders to improve interoperability and the use of AI-enabled tools in clinical care.

Sincerely,

Ly Tran
CEO
BelleTorus Corporation
ltran@belle.ai