Issue: Across federal and state governmental entities and across the private sector, a wide variety of connected technology-enabled solutions[1] for improved patient care and health populations are either in use or in development. Currently, the American Medical Association's CPT® Telehealth Services Working Group is working to capture the practices and procedures of telehealth services that physicians can provide in a code.

Objective: Develop a consensus document that defines the key connected health term "asynchronous."

Methodology: The Connected Health Initiative (CHI), an initiative of ACT | The App Association focused on supporting advancements in connected health, has aggregated a wide range of connected health terminology and definitions which are appended to this strawman. From this and input from CHI members, we aim to develop a consensus document capturing key connected health terminology and relationships amongst and between these terms, beginning with the term "asynchronous."

Proposed Text:

A well-established and growing body of clinical evidence suggests that enhanced use of connected health technology improves care, reduces hospitalizations, helps avoid complications, and improves satisfaction, particularly for the chronically ill. As these products and services are marketed and deployed, and captured in statutory and regulatory definitions across the federal and state contexts, a wide range of terminologies and definitions have emerged (see appended document).

The existing definitions used to capture an aspect (or all) of connected health are inconsistent and have unfortunately led to confusion and in some cases has limited the ability of American patients to leverage the most effective technological solutions available in their treatments. For example, without guidance from statue, the Center for Medicare and Medicaid Services (CMS) continues to restrict Medicare-reimbursable "telehealth" services to "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication".[2] Recently, the Medicare and CHIP Reauthorization Act (MACRA) has instructed CMS to incorporate "telehealth and remote patient monitoring" into the new value-based system. The CPT process is well-positioned to contribute to the accurate capture of medical practices that include these new tools, including asynchronous/store and forward technology.

The following definition is proposed:

- Asynchronous/Store and Forward: the sharing of data from one party to another through the use of a device or software that records, stores, and then sends such data via any communications or technological means.

[1] For the purposes of this document, "connected-technology enabled solutions for improved patient care and health populations" refer to those technologies that are:

A) Considered medical devices under the FDA per view and have been cleared by the FDA

B) Technologies that are considered "wellness" devices and considered a medical device under enforcement discretion per FDA MMA guidance of 2013

C) Those mobile medical apps referenced by the FDA MMA guidance of 2013 that help patients and physicians monitor chronic conditions, overall health, and population health (in the case of the physician)

[2] 66 Fed. Reg. 55281.

Asynchronous/Store and Forward use cases include:

- **Use Case 1: Population Health Management Software(Aces.md)**

  Assumptions: The Company and The Physician have a partnership or Business Associate Agreement. The Physician recommends the app to The Patient. The Patient utilizes their own wellness device, like a step tracker, and a medical device, like a glucometer, that The Physician prescribed.

  - **The Company** offers software that integrates Bluetooth medical devices (e.g., smart inhalers and heart monitors) to offer care providers a complete picture of the **Patient's** health through the capture of their biometric data. The **Company's** software platform communicates this critical biometric data to the **Physician** on a periodic basis.
  - **The Medicare Patient**, after discussion with their **Physician** about a care plan, agrees to utilize the company's software. **Patient** utilizes a device considered a medical device under Enforcement Discretion per FDA MMA guidance prescribed by their **Physician**. **Patient** wears a device that gathers biometric data automatically and periodically. No further action past checking that the item is on/functioning is required.
  - **The Physician**, after prescribing the company's software to the **Patient**, uses the company's software platform to monitor and review the patient's biometric data as needed, utilizing automatic alerts for instances where the biometric data exceeds certain thresholds. If triggered, the physician's office initiates an outreach procedure to **The Patient** in order to implement and care plan or intervene before a health event occurs.

- **Use Case 2: Connected Medical Device (AirStrip)**

  Assumptions: The Company and The Physician have signed a Business Associate Agreement. It is up to The Physician's discretion where and when the technology is utilized. Outside of granting permission for access, The Patient is not required to utilize the software outside of the treatment facility.

  - **The Company** offers software that integrates data systems, sources, and data types to create mobile interoperability. **Company** provides platform for care collaboration between **Physicians**, and active engagement between **Physician** and **Patient**.
  - **The Patient**, after discussion with their physician about a care plan, agrees to utilize the **Company's** software. **Patient** grants approved **Physicians** access to Electronic Medical Records (EMRs), and thus receives more complete and informed care.
  - **The Physician**, after prescribing the company's software to the patient, uses the **Company's** software platform to monitor and review the patient's biometric data as needed, utilizing data sources (like EMRs and body sensors) to create targeted treatment decisions. Platform prepares/informs **Physician** of any possible impending medical emergencies for **Patient** based on records provided and the current biometrics the Physician gathers in person. *These activities are paid for by unbundled CPT codes that ensure coverage for: (1) development of a care plan; and (2) evaluation and management of patient vitals.*

- **Use Case 3: Connected Medical Device (Rimidi)**

  Assumptions: The Company and The Physician have a Business Associate Agreement.

- **The Company** offers software that provides a platform for the patient to input and the physician to analyze biometric data updates, providing a more complete picture of a patient's/disease's history and development. Similarly, The Company provides a back-end dashboard for The Physician to use where the information is aggregated in such a way that The Physician can use it to help determine care plan and treatment methods.
- **The Patient**, after discussion with their physician about a care plan, agrees to utilize the company's software. **Patient** utilizes a device considered a medical device under Enforcement Discretion per FDA MMA guidance to store and display glucose and lifestyle data. **Patient** uses software reminders to stay up-to-date with preventative tests and services, and receive feedback from physician more frequently than in-person appointments.
- **The Physician**, after prescribing the company's software to the patient, uses the company's software platform to monitor and review the patient's care plan. **Physician** uses software platform to see how the **Patient's** treatment has affected their biometric data, and prescribes and documents further patient education when applicable. **Physician** uses software platform to alert **Patient**, or alter care plan, if their biometric data exceeds certain thresholds. *These activities are paid for by unbundled CPT codes that ensure coverage for: (1) development of a care plan; and (2) evaluation and management of patient vitals.*

- **Use Case 4: Connected Medical Device (Resmed)**

  Assumptions: The Company and The Physician have signed a Business Associate Agreement.

  - **The Company** offers a medical device that through cellular connectivity, provides features to the **Patient** that work to treat their sleep disorders, and provides the **Physician** biometric updates on the **Patient's** development and progress or lack thereof.
  - **The Patient**, after discussion with their physician about a care plan, agrees to utilize the company's device. **Patient** utilizes the FDA cleared device to treat their sleep disorder. **Patient** uses device and its provided features and therapies before and during sleep to gradually change and improve their sleep disorder and its symptoms.
  - **The Physician**, after prescribing the company's software to the patient, uses the company's software cellular connectivity to monitor and review the patient's progress and use of the device. **Physician** uses software to assess the effect of the device on the **Patient's** diagnosis and treatment plan. **Physician** uses software platform to alert **Patient**, or alter care plan, if their biometric data exceeds certain thresholds. *These activities are paid for by unbundled CPT codes that ensure coverage for: (1) development of a care plan; and (2) evaluation and management of patient vitals.*

- **Use Case 5: Connected Wellness Device (Apple)**

  - **The Company**offers a wearable device and software considered a medical device under enforcement discretion per the FDA MMA guidance that records **Patient's** biometric data and allows the **Physician** to analyze the recorded data.
  - **The Patient**, after discussion with their physician about their health and wellness, decides to utilize the company's software and wearable device. **Patient** wears the device daily to record biometric data (ie. Heart rate, sleep patterns,). **Patient** uses the device's software to stay up-to-date with treatment and health reminders and track their progress.

- **The Physician**, with **The Patient,** can review the data collected by the company to get a better overall picture of **The Patient's** health. **Physician can** use the software platform to see how the **Patient's** biometric data has changed, and prescribes further patient education when applicable. In this case, **Physician** only has access to this data if **The Patient** chooses to share it with **The Physician** at the point of care or between visits.