Guiding Principles On Virtual Care

Consumer Technology Association™
### SUMMARY OF THE GUIDING PRINCIPLES ON VIRTUAL CARE

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<th>CORE PRINCIPLES</th>
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| Inform consumers and secondary users, such as providers of healthcare services, of how the virtual care tool is to be utilized to achieve specified outcomes and provide a seamless and efficient engagement. | • Determine the best means to effectively inform consumers of how best to utilize the virtual care tool.  
• Effectively inform consumers of how to use the virtual care tool.  
• Inform consumers of multi-use case for the virtual care tool.  
• Inform consumers of benefits and risks of using the virtual care tool.  
• Inform consumers of limitations in the use of the virtual care tool.  
• Align clinical protocols with how best to use utilize the virtual care tool to achieve intended outcomes.  
• Provide healthcare service providers with appropriate care applications and efficacy data to ensure optimal outcomes in the use of the virtual care tool.  
• Provide consumers with potential costs associated with virtual care tools. |
| Design the virtual care tool to allow for users to ask questions about appropriate use and functionality. | • Implement a means to engage users of virtual care tools to assist in understanding the appropriate use and functionality of the virtual care tool.  
• Implement a process for managing consumer inquiries with published response. |
| Design the virtual care tool to allow for universal access. | • Apply universal design principles, and develop virtual care tools, in light of standards and guidance regarding access and accommodation to ensure accessibility of the virtual care tools by as many consumers as possible. |
| Build mechanisms to troubleshoot products when the technology fails. | • Implement plans to continue consumer engagement in the event technology fails.  
• Carefully calibrate troubleshooting mechanisms to the functionality of the virtual care tool and reflect the clinical intensity of the use-case.  
• Inform consumers of scheduled maintenance/outages.  
• Inform consumers of expected changes in the performance of the virtual care tool. |
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## CORE PRINCIPLES

**CONTINUITY OF CARE**

A virtual care tool should not interrupt or inhibit appropriate patient engagement within a total care plan, and where possible should promote continuity of care.

- Use of the virtual care tool should fit in a consumer’s overall care continuum.
- Where possible, virtual care tools should allow:
  - Providers to draw information from a previous encounter with a consumer through use of the virtual care tool to ensure a seamless service.
  - Consumers to request, and virtual care providers the ability (subject to consent) to share, a consumer’s information provided via a virtual care tool with a consumer’s other healthcare providers.

Virtual care tool developers and providers should ensure consumers have access to their data vis-à-vis the virtual care tool, and to the extent allowable, direct who else may have access.

- Remain informed of and adhere to state and federal requirements regarding a consumer’s access to his/her health information, and requirements regarding disclosure of health information.

**PRESCRIBING**

Virtual care tools should not facilitate inappropriate prescribing and/or dispensing practices.

- Actively monitor and adhere to the dynamic regulatory requirements for prescribing and dispensing of prescription medications via virtual care tools.

Virtual care providers should collect complete and accurate information, whether from the consumer or from the consumer’s medical records (as available), to allow the virtual care provider to positively identify and appropriately prescribe medications to a consumer. Understand that the information provided from the consumer in a virtual care encounter is in part determinative of the quality of the outcome (e.g., ultimately the quality of the consumer’s health outcome).

- Consumers should provide accurate, complete and thorough information to the virtual care provider.
- Build in checks and reminders to assist consumers in providing complete and pertinent information, while documenting completely and accurately the information obtained from consumers.

**PRIVACY AND SECURITY**

Virtual care tool developers should ensure that use of the virtual care tool complies with applicable federal and state privacy and security laws.

- Remain informed of federal and state privacy and security laws applicable to the use of the virtual care tool, and ensure that use of the virtual care tool complies with applicable law. For more information, please see [CTA’s Guiding Principles for the Privacy of Personal Health and Wellness Information](https://www.cta.tech).

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[CTA’s Guiding Principles for the Privacy of Personal Health and Wellness Information](https://www.cta.tech)
I. Introduction
As the healthcare industry continues to push the bounds of how consumers engage with healthcare services, there continues to be a demand for innovative healthcare solutions that increase the convenience and accessibility of healthcare services, improve the quality of healthcare services and healthcare delivery systems, and ultimately assist in improving health outcomes for consumers. Virtual care has increasingly become one of the major healthcare solutions in meeting these growing demands of the healthcare industry. Through virtual care tools, consumers are able to receive, and providers are able to deliver, healthcare services outside of the traditional context. Virtual care tools enable healthcare providers to provide consultations to consumers across state lines, to monitor patients and provide instant feedback and medical advice to patients and medical staff in a healthcare facility without actually being present in the facility, and to track and aggregate consumer health information. Just the same, through the use of virtual care tools consumers are able to better track and manage their own health in convenient ways.

Although virtual care tools continue to grow in both number and capabilities, there remains a need for transparent and standards-based evaluation and deployment of virtual care tools that bring greater clarity to their development and use (for developers, providers, and consumers). To that end, the Consumer Technology Association (“CTA” or “we”) recommends that developers of virtual care tools, and healthcare professionals who may use or benefit from a consumer’s use of a virtual care tool, incorporate these Guiding Principles on Virtual Care (“Principles”) into their technologies and practices. Awareness of these Principles through the development and deployment of virtual care tools will help to (i) set expectations of the use of the tool, (ii) mitigate risks that consumers may perceive with respect to the virtual care tool, and (iii) track and optimize health outcomes through the use of the virtual care tool.

CTA intends these Principles to be baseline recommendations that are designed to address virtual care tools that include some degree of consumer engagement, whether patient or provider, in the context of healthcare services delivery or health or well-being maintenance. Virtual care tool developers and providers should remain flexible on how to implement these Principles so they can account for differences in technology, products, and services, and account for dynamic health regulatory regimes. CTA encourages virtual care tool developers and providers to continually evaluate their virtual care tool and its use, and also encourage virtual care tool developers and providers to maintain an ongoing dialogue with consumers to discuss the value of their technologies.

In applying these Principles, consumers, developers of virtual care tools, healthcare professionals who may use or benefit from a consumer’s use of a virtual care tool, and other parties who may have an interest in the use of virtual care tools, should understand that “virtual care” is a broad term that encompasses all the ways technology is being designed to address health matters. In these Principles, the term “virtual care tools” refers to all products and services in the delivery of virtual care. Further, these Principles take into consideration and differentiate from existing best practices for virtual care tools that have been prepared by other professional associations and organizations.
II. Scope and Application

The Principles are:

• Voluntary considerations for consumers, developers of virtual care tools, healthcare professionals who may use or benefit from a consumer’s use of a virtual care tool, and other parties who may have an interest in the use of virtual care tools, such as third-party payors.

• Based on concepts and best practices currently present and developing in the U.S. regarding the provision of virtual care and consumer protection.

• Offered to complement, not supplant, the applicable federal and state legal requirements and regimes, and assist in bridging the gap in legal and regulatory guidance and consumer expectations.

• Intended to educate consumers, providers, payors and others about virtual care engagements to enable them to make informed choices about the virtual care tools with which they choose to interact, and written and formatted in a way that the average consumer can easily understand.

• Intended to help define the setting of expectations and responsibilities of consumers, providers, developers and others in the use of virtual care tools.

• Intended to ensure the appropriate use of virtual care tools and thereby support the credibility of virtual care tools with consumers and the broader healthcare industry.

The Principles are not legal requirements, nor are the Principles a substitute for legal compliance. Additionally, certain Principles may not be applicable to certain virtual care tool providers or developers. Therefore, virtual care tool developers and providers should evaluate how the Principles are applicable to their virtual care tools and operations, and seek further guidance as necessary. Likewise, consumers should seek further guidance from the virtual care tool developer or their healthcare provider to determine how the Principles are applicable to the virtual care tool that they are using and for the goals the consumer hopes to achieve in using the virtual care tool.

III. Principles on Virtual Care

A. Consumer Engagement

1. Inform consumers and secondary users, such as providers of healthcare services, of how the virtual care tool is to be utilized to achieve specified outcomes and provide a seamless and efficient engagement.

There are many virtual care tools from which a consumer may choose. Once consumers determine the virtual care tool to use and the purposes they intend to achieve, the consumer should use the virtual care tool in accordance with the ways in which the virtual care tool developer or provider expects and intends for it to be used (given the purpose of the virtual care tool).

CTA recommends:

• Virtual care tool developers determine and deploy the best means to effectively inform consumers, based on how the virtual care tool developer or provider engages with consumers, on how best to utilize the virtual care tool. Virtual care tool developers should remain cognizant of the fact that consumers may not fully or timely read the various informational materials regarding the virtual care tool. For example, certain informational material, such as the terms of use, while useful and informative, may not serve as the best place to effectively communicate important information to a consumer on how to
effectively use the virtual care tool. Virtual care tool developers and providers may better communicate use of the virtual care tool through prompts within the virtual care tool, or such other methods as the virtual care tool developer or provider deems necessary and effective.

- Virtual care tool providers inform consumers of multi-use cases for the virtual care tool (e.g., virtual reality ("VR") therapeutics, accessibility tools), if applicable.
- Virtual care tool developers effectively inform consumers on how best to utilize the specific virtual care tool to ensure the optimal outcome for the consumer.
- Consistent with best practices, virtual care tool developers inform consumers of the potential benefits and risks associated with using the virtual care tool, based on input from appropriate healthcare professionals and review of current research, as needed.
- Virtual care tool developers effectively inform consumers of potential limitations if the virtual care tool is not utilized as intended. For example, if the virtual care tool requires a certain computer operating system or Internet bandwidth, then the virtual care tool developer should highlight that not having the required items may limit the functionality of the virtual care tool or render the virtual care tool inoperable.
- Virtual care tool developers align their clinical protocols with how best to utilize the virtual care tool to meet the intended outcome. Such clinical protocols will set expectations for the use of the virtual care tool, and may also further inform (as necessary) consumers of necessary steps in utilizing the virtual care tool. For example, virtual care providers may prompt the consumer to input certain information into the virtual care tool, to which the virtual care tool developer/provider will review in a certain amount of time.
- Virtual care tool developers provide service providers with appropriate care applications and efficacy data to ensure the optimal outcome if a virtual care tool is to be used in conjunction with existing healthcare services or providers, or if it is to be used primarily by a healthcare professional.
- Virtual care tool developers and providers provide information regarding the potential costs associated with using the virtual care tool, and inform the consumer that there may be additional variable costs associated with the virtual care tools (e.g., internet, text messaging and data charges).

2. Design the virtual care tool to allow users to ask questions about appropriate use and functionality. As consumers engage with virtual care services through virtual care tools, there will inherently continue to be questions that arise regarding the use and functionality of the virtual care tool.

**CTA recommends:**

- Virtual care tool developers implement a means to engage users of virtual care tools to assist the user in understanding the appropriate use and functionality of the virtual care tool (e.g., support line, virtual assistant, or customer service mailbox).
- Virtual care tool developers have a process for managing consumer inquiries with published responses (e.g., a notice to consumers that they will receive a response to their inquiry within a specified period of time that the developer can achieve).

3. Design the virtual care tool to allow for universal access. Consumers have varying needs when utilizing virtual care tools. To help facilitate the ability for consumers
to effectively utilize a virtual care tool and ensure virtual care tools are accessible to as many consumers as possible, CTA recommends virtual care tool developers apply universal design principles and develop tools in light of guidance and standards regarding access and accommodation (e.g., guidance and standards of the Americans with Disabilities Act and the accessibility advocacy community).

4. **Build mechanisms to troubleshoot products when the technology fails.**
As is the case with all technology, virtual care tools are subject to potential technological issues that may inhibit the consumer’s ability to use a virtual care tool.

**CTA recommends:**
• Virtual care tool developers have plans to continue consumer engagement in the event the technology fails. The plans for technology failure should be clearly articulated to the consumer (and secondary users as required) prior to beginning a virtual care engagement.
• Troubleshooting mechanisms be carefully calibrated to the functionality of the virtual care tool and reflect the clinical intensity of the use-case. For example, in the telemedicine context, a virtual care tool could provide for, or prompt the creation of, an alternative means of engagement between a healthcare provider and consumer, such as prompting the consumer to provide an alternative telephone number. Similarly, in the context of a diabetes management tool that transmits data to a provider, the virtual care tool should inform the consumer of what to do if the virtual care tool fails to transmit data (e.g., check Internet, reset the tool, or send the information via secure email).
• Virtual care tool developers inform consumers of scheduled maintenance or scheduled outage, and include plans for continued consumer engagement in the event of any disruption in service.
• Virtual care tool developers provide consumers with information regarding any expected changes, intended or otherwise, in the performance of the virtual care tool that derive from maintenance or enhancements to the virtual care tool.

B. **Standard of Care**
1. **Ensure that the virtual care tool works within, and use cases are described within, applicable best practice guidance from regulatory bodies and professional associations.**

The standard of care within sub-sectors of the healthcare industry are developed and enforced by various regulatory bodies, and vary depending on the state and the type of healthcare services being provided. For example, the standard of care for a psychologist providing behavioral health consultations will differ in certain ways from the standard of care for a physician proving primary care services. State and federal regulatory bodies, as well as industry associations, have published guidance on the standard of care.

**CTA recommends:**
• Virtual care tool developers and providers remain informed of the applicable laws, policies, and available guidance regarding the development and implementation of the virtual care tool.
• Virtual care tool developers and providers ensure virtual care tools work within established practice guidelines allowing virtual care providers to act within a consistent framework.
2. If a virtual care tool addresses a specific condition subject to a known standard of care, then the virtual care tool should be used consistent with or as an enhancement of the standard of care.

Virtual care tool developers and providers should remain diligent in understanding the dynamic regulatory regimes applicable to their tools. In complying with a regulatory regime, CTA recommends:

• Virtual care tool developers inform consumers and providers of how the virtual care tool is consistent with or enhances the applicable standard of care. For example, virtual care tool developers may provide consumers with an “information sheet” which contains information such as:
  o The purpose for which the virtual care tool is commonly used.
  o Who may benefit from the use of the virtual care tool.
  o Guidance on how to integrate the virtual care tool into the consumer’s daily routine or the common care regimen.
  o What type of healthcare professional should be informed of the consumer’s decision to use the virtual care tool (e.g., primary care physician or care manager).
  o Guidance applicable to the information obtained or used through the virtual care tool (e.g., the American Diabetes Association’s guidelines on blood glucose ranges and standards for managing blood glucose and the American Hospital Association’s guidelines on antimicrobial stewardship).
  o If applicable, a statement acknowledging that the virtual care tool has not been evaluated by the Food and Drug Administration, and that the tool is not intended to diagnose, treat, cure, or prevent any disease.

3. Consistent with best practices, virtual care tool developers should inform users of potential benefits and risk associated with using the virtual care tool based on input from appropriate healthcare professionals and review of current research, as needed. Particular care should be taken to inform users of potential risks if the use of the virtual care tool is intended to change an established standard of care, and if the outcomes of using the tool are not yet well understood.

The fast paced development and deployment of technology in healthcare has continued to affect the standard of care to which healthcare providers are held in the provision of healthcare services. Where once healthcare providers only had the ability to provide healthcare services in-person, consumers may now access and transmit to a provider up-to-the-minute data and connect with a provider across the country using virtual care tools. With all healthcare services, there are inherent risks and benefits. Consistent with required practices in the provision of healthcare services, CTA recommends virtual care developers and providers inform consumers of the benefits and risks of utilizing the virtual care tools. Virtual care developers and providers should remain even more prudent in informing consumers of potential risks of using a virtual care tool that is intended to change the known standard of care.
C. Quality

1. Understand what “quality” means with respect to (i) the use of the virtual care tool, (ii) the conditions addressed by the virtual care tool, and (iii) the impact of the virtual care tool on the consumers’ overall quality of life.

The healthcare industry continues to focus on quality as a metric of evaluating healthcare products and services. In the provision of healthcare services, state and federal regulatory bodies have defined metrics relative to the quality of care outcomes and processes in a traditional patient-provider engagement. Increasingly, providers of healthcare services are being held accountable for the quality of their services through reimbursement and other mechanisms. Regulatory bodies have also provided guidance on the requirements regarding quality of care in the provision of virtual care.

**CTA recommends:**

- Virtual care tool developers and providers assess what constitutes “quality” relative to the virtual care tool. In assessing quality, virtual care tool providers and developers should assess various aspects of “quality,” including, for example, assessing non-clinical “quality” aspects of a virtual care tool and its use with respect to the impact on a consumers quality of life (e.g., assessing the impact of the virtual care tool on the quality of a consumer’s life by indirect cost avoidance, improved job productivity, medication adherence, or reduced absenteeism), and aspects of quality regarding the use of the virtual care tool (e.g., functionality, maintenance, and accessibility).

- Where appropriate, virtual care tool developers develop quality metrics in conjunction with healthcare providers, and assess the quality of the virtual care tool based on traditional and additional metrics (e.g., clinical outcomes, consumer engagement, technology use, peer review, and consumer feedback). Quality metrics for the virtual care tool should be used to track and demonstrate quality, which may include incorporating mechanisms into its operations to ensure it is delivering and maintaining quality services to consumers. For example, in the telemedicine context, companies may implement peer review or quality review committees, which are charged with assessing (i) documentation (e.g., medical records), (ii) communication with consumers, and (iii) follow-up. Implementing quality metrics will assist virtual care tool developers and providers in addressing consumers concerns and expectations.

- Virtual care tool developers should develop mechanisms to obtain consumer and provider feedback in order to measure the quality of the virtual care tool and use of the virtual care tool. Depending on the modality through which the virtual care tool is used, feedback relative to quality of the virtual care tool may include, but is not limited to, feedback on provider response times, technology uptake times, ease of use by the consumer, quality of healthcare services through the use of the tool, etc.

- Consumers and providers of health services remain informed about how the utilization of a virtual care tool can impact the quality of the consumer’s health and the healthcare services being provided by healthcare professionals.

2. Continually address improvement in the implementation of the virtual care tool.

The evaluation of the “quality” of a virtual care tool and its use is an iterative process requiring continuous input and feedback from consumers, providers, and other parties.
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CTA recommends:

• Virtual care tool developers and providers implement appropriate training and evaluation of providers, consumers, or caregivers, as applicable, to ensure appropriate use of the virtual care tool.

• Virtual care tool providers implement peer review or internal quality review processes.

• Virtual care tool providers establish a feedback loop to allow for continual communication within the organization and with consumers (including providers) to allow for quick identification of problems and development of solutions.

3. Virtual care tool providers should be conscious of how addressing quality of the virtual care tool or its use may in turn address population-based outcomes.

One of the potential effects of addressing quality as it relates to virtual care tools is that virtual care providers may be able to manage health outcomes across a population of patients. In effect, the quality of the virtual care tool and the use of the tool may increase access to care for a population of patients, or may increase the effectiveness of the care being delivered to a population of patients. CTA recommends that virtual care tool providers remain cognizant of how addressing quality of the virtual care tool and its use assists in addressing population-based health outcomes.

4. Virtual care tool developers and providers should ensure that the people that need to monitor quality (e.g., providers, executives, and compliance staff) have the appropriate access to the metrics to measure quality.

Continuous assessment of the quality of virtual care tools requires buy-in from various stakeholders within an organization.

CTA recommends:

• Virtual care tool developers and providers ensure that all the people that will assess the quality of a virtual care tool or its use have access to the metrics by which quality is measured.

• Virtual care tool developers and providers inform all the people that need to monitor the quality of the virtual care tool and its use on how to assess quality based upon the established metrics.

D. Continuity of Care

1. A virtual care tool should not interrupt or inhibit appropriate patient engagement within a total care plan, and where possible should promote continuity of care.

The healthcare industry continues to find ways to enhance quality of healthcare services, reduce costs, and overall improve health outcomes. A mainstay of this continuing effort, which remains important to both providers and consumers, is enhancing the continuum of care. As such, virtual care tools should promote continuity of care, and should not interrupt or inhibit appropriate patient engagement within a total care plan.
CTA recommends:

- Virtual care tools have sufficient functionality to be able to fit in a consumer’s overall care continuum.
- Virtual care tools allow providers to draw information from a previous encounter with a consumer through use of the virtual care tool to ensure a seamless service. For example, in the telemedicine context, a consumer that undergoes a telemedicine visit in March might expect that if he/she undergoes a telemedicine visit in May, then the provider will be able to look up the previous telemedicine encounter to understand the consumer’s health history. The ability for a provider to review the notes of a previous encounter helps to create a seamless process.
- Consumers have the ability to request, and virtual care providers have the ability (subject to consent) to share, a consumer’s information provided via a virtual care tool with a consumer’s other healthcare providers. Note that certain states require that certain healthcare information provided to a virtual care provider be shared with a consumer’s other providers (e.g., primary care providers).

2. Virtual care tool developers and providers should ensure consumers have access to their data vis-à-vis the virtual care tool, and to the extent allowable, direct who else may have access.

States have varying requirements with respect to a consumer’s access to his or her health information. CTA recommends virtual care tool developers and providers remain informed of and adhere to applicable legal requirements regarding a consumer’s access to his/her health information, and requirements regarding disclosure of health information.

E. Prescribing

1. Virtual care tools should not facilitate inappropriate prescribing and/or dispensing practices.

Virtual care tool providers should understand that the requirements regarding electronic prescribing, transmission, and filling of prescription medications, including controlled substances, vary state to state and federally. Additionally, the laws applicable to prescribing prescription medications through virtual care tools continues to develop. For example, in November 2019, California enacted a law that altered the previous standard for prescribing, dispensing and furnishing dangerous drugs (including any prescription medication) such that providers may prescribe medications via telehealth as long as there is an “appropriate prior examination and a medical indication.”

CTA recommends virtual care providers continue to monitor and adhere to the dynamic regulatory requirements for prescribing and/or dispensing of prescription medications via virtual care tools.

2. Virtual care providers should collect complete and accurate information, whether from the consumer or from the consumer’s medical records (as available), to allow the virtual care provider to positively identify and appropriately prescribe medications to a consumer.

Prescribing of medications through virtual care tools can be impacted in several different ways. However, one of the primary considerations is whether an encounter between a virtual care provider and a consumer via a virtual care tool is adequate to establish a patient-provider relationship when one did not previously exist, and whether the information obtained by the virtual care provider about the consumer is sufficient
to appropriately prescribe a medication to the consumer. Consumers and virtual care providers should understand that the information provided from the consumer in a virtual care encounter is in part determinative of the quality of the outcome (e.g., ultimately the quality of the consumer’s health outcome).

**CTA recommends:**

- Consumers provide accurate, complete and thorough information to the virtual care provider.
- Virtual care providers build in checks and reminders to assist consumers in providing complete and pertinent information, while documenting completely and accurately the information obtained from consumers.

**F. Privacy and Security**

Virtual care tool developers and providers understand that they must be good data stewards to maintain consumer trust. As such, CTA recommends that virtual care tool developers and providers ensure that use of the virtual care tool complies with applicable federal and state privacy and security laws. For more information on the principles applicable to the privacy of personal health information, please see CTA’s Guiding Principles for the Privacy of Personal Health and Wellness Information.