SPECIAL INTEREST GROUP

Making the Case for Non-Discriminatory Regulation and Reimbursement for Home Testing

White Paper and Terms Guide by the American Telemedicine Association Home Testing Special Interest Group (SIG)

David P. Ryan and Brandon T. Johnson, SIG Co-Chairs

www.americantelemed.org

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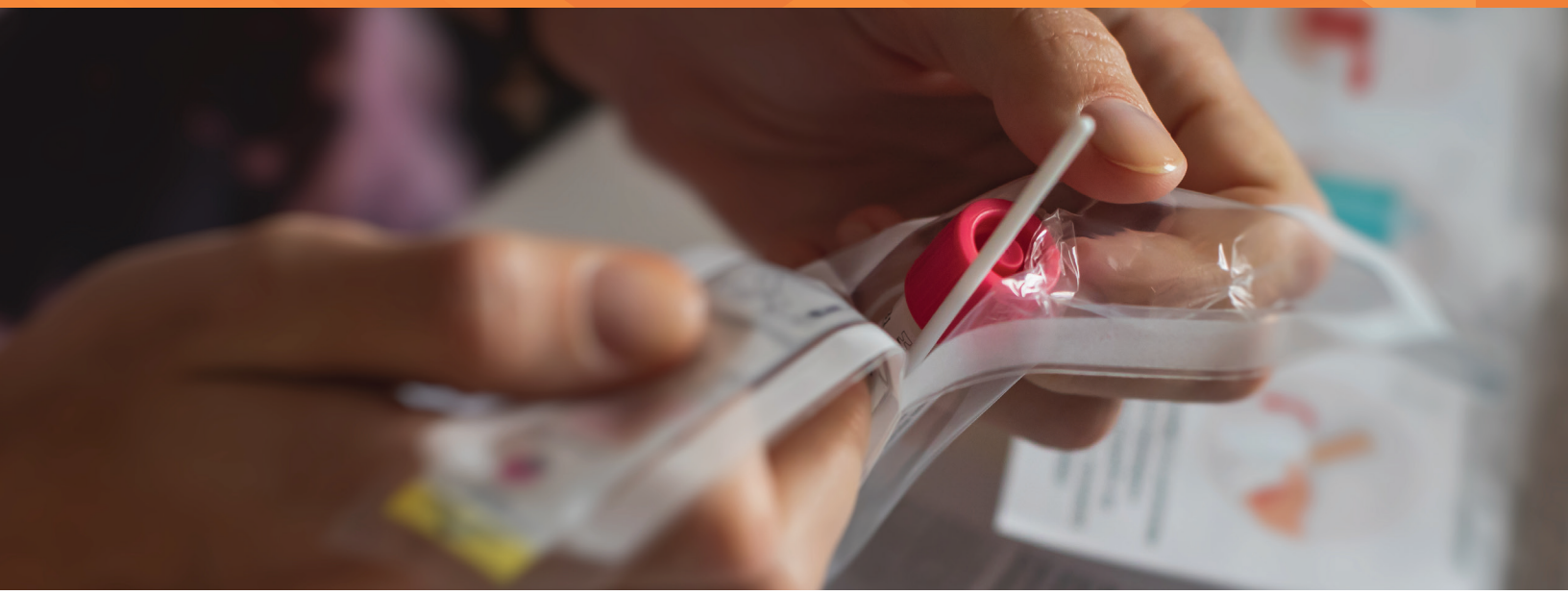


Executive Summary

The following document offers a statement from the American Telemedicine Association (ATA) with regards to regulation and reimbursement for at-home medical testing services, developed in consensus by members of the ATA Home Testing Special Interest Group (SIG).

The statements contained within this document refer exclusively to sample collection and/or testing prescribed by a provider for purposes of screening, diagnostic support and monitoring, performed outside a clinical setting by the patient or other non-clinician.

The ATA's view on the regulation of Home Testing products, elaborated below, is that **1)** providers and patients are best able to determine what venue is appropriate for home collection and/or testing, and **2)** that regulatory practices should not artificially disadvantage or advantage methods for providing Home Testing in conjunction with Telemedicine to address unmet patient needs.

The ATA's view on reimbursement for Home Testing products is **3)** that it should be fair and reasonable for those products prescribed by a provider for use in the home for screening, diagnosis and monitoring.

Introduction

Despite the widespread recognition of the convenience and benefits of telemedicine and home sampling to patients before the COVID-19 pandemic, the boundaries between medical tests performed in healthcare and consumer settings were clear. It is notable that only a limited number of tests, such as diabetic monitoring, had become well established in the home setting. However, since the onset of the pandemic in early 2020, these boundaries have become much more blurred. Terms which were not previously familiar to consumers, such as antigen testing, PCR testing, accuracy, sample, and sensitivity, have now become a part of our common vocabulary. In addition, consumers have demonstrated that they can successfully perform a series of simple steps for using a home test as directed in writing or with a smartphone app. As such, the consumer has begun to exercise choices and preferences for these tests[i] based on their accuracy, accessibility, and ease of use.[ii] In parallel, healthcare providers are increasingly accepting test data that does not originate from a reference laboratory. Furthermore, providers are recognizing the reduction of in-clinic appointments that is afforded by home testing, and the concomitant better use of scarce healthcare resources.[iii]

Alongside the shift towards at-home testing accelerated by the pandemic, there is a step change in the adoption of telehealth for patient care.[iv] The share of Medicare visits conducted through telehealth increased 63-fold, from approximately 840,000 in 2019 to 52.7 million in 2021. While e-visits and virtual checkups reached their highest in Q1-Q2 2020 and have since declined, as of Q1 2021, there was still a total net increase from before the pandemic. These shifts in telemedicine and home sampling intersect at a huge potential opportunity to improve patient satisfaction, clinical outcomes and lower healthcare costs.

At-home testing, where the patient is prescribed a test prior to the telehealth visit, enabling them to self-collect samples or perform the entire diagnostic process themselves from sample collection to result, is beneficial to the patients and healthcare network in a number of ways.[v] This triaging step can result in a decrease in the time from symptom onset to treatment and a reduction of the burden of a physical visit to a clinic or laboratory. Home Testing products, including both products where samples are collected at home and tested at a lab and where samples are collected and tested in the home, as a supplement to Telehealth are essential to enabling broader access to high quality health care. Likewise, leveraging telehealth to supervise sample collection at home and interpretation of results could expand the potential of tests that can be effectively done outside of a clinic or healthcare facility. Telemedicine supported by Home Testing also enables many disadvantaged populations, such as those in rural areas, and / or of lower socio-economic status, to have access to higher quality care with fewer interruptions to their lives. Virtual appointments supported by medical tests mean less travel, less waiting time, more flexible timing and reduces or eliminates the need to arrange childcare during the appointment. This means busy parents with multiple jobs can get the care they need without missing work or their child's play or sport event.

To date, lab test availability in the home has been limited and lab tests are not generally available for telehealth encounters. While the COVID-19 pandemic has greatly accelerated the market availability of over-the-counter home sample collection and home testing solutions, either with or without a prescription, adoption has been relatively modest. Industry and the regulating agencies are aligned in their interest in enabling high quality safe products to have a clear path to market. Enabling the routine prescribing of these at-home diagnostic tests, along with associated reimbursement, as is already available for testing in a clinical setting, would enable this change and facilitate the realization of the benefits.

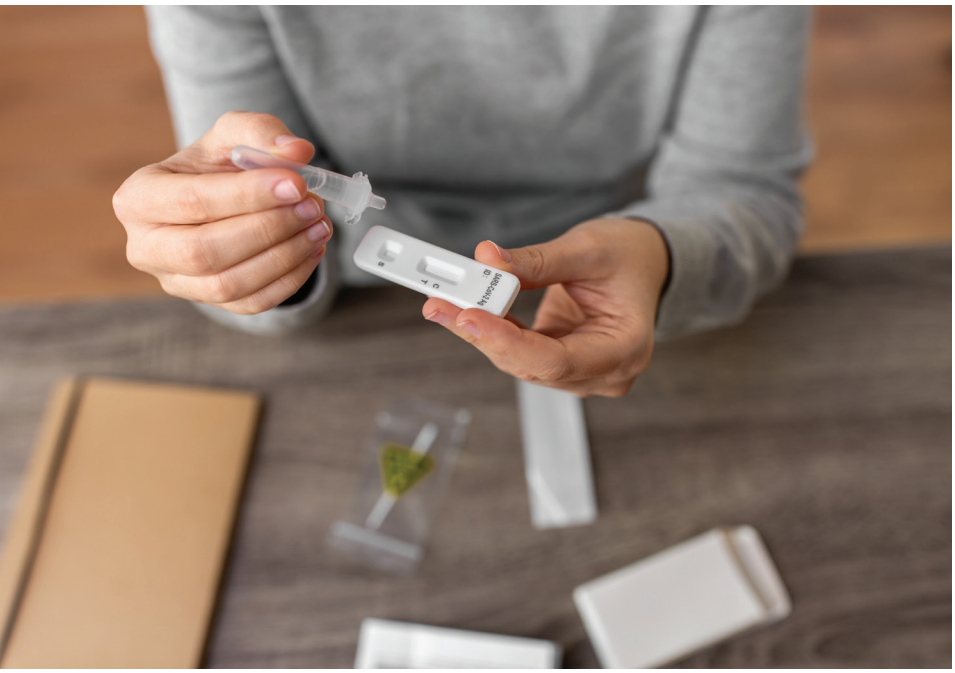
The Home Testing Special Interest Group (SIG) of the American Telemedicine Association (ATA) brings together medical, scientific, technology solution, laboratory and regulatory experts to address barriers to adoption and to accelerate the use of home testing as a part of virtual care. This manuscript sets out the thoughts of this group for home testing prescribed by a provider, where sample collection and/or testing for purposes of screening, diagnostic support and monitoring are performed outside a clinical setting by the patient or other non-clinician. Specifically, the document considers the regulatory and reimbursement framework for prescribed home testing, such that this approach should not be artificially advantaged, or disadvantaged compared to existing in-clinic testing approaches. In addition, in order to facilitate the broader conversation around the processes associated with home sampling, this document sets out definitions of a number of terms associated with this activity.

Regulation: Provider and Patient Choice

The ATA's view on prescribed home testing products is that patients should be enabled to self-test wherever they are, when they are in need. Be that at home, when traveling, when needed to enter a workplace, school or any requiring venue, whether the appropriate test for that moment be:

- Self-Collected and sent out for processing with eventual electronic results
- Self-Collected with immediate data / results
- Require or not require follow-on medical consultation

As such, we contend that providers and patients in partnership are best able to determine what venue is appropriate for home sample collection and/or testing. The recent implementation of home testing for antigens and antibodies during the COVID-19 pandemic has clearly demonstrated the ability of patients to successfully manage nuance that comes with at-home collection and testing. However, the early stages of the pandemic showed us that there is an understandable concern from healthcare providers that some individuals will not be able



to perform the necessary procedures of sample collection, testing or shipping to the required standard, rather than them taking a standpoint that most are fully capable. We contest that this concern can not only be ameliorated by high quality training and support, but that the advantages of being able to reach communities who are currently underserved by current clinic centric approaches outweigh the risks. Furthermore, other solutions to enable reassurance that a high-quality sample is collected from the correct person include considerations around whether the sampling should be supervised, or unsupervised.

In addition, the repeated collection of samples by an individual in a non-clinical setting will increase their self confidence in the process and that of the provider that the procedures are being performed correctly. The success of the COVID home testing program demonstrates that these issues can be addressed.

As demand for testing continues to increase and the utilization of telehealth continues to grow, the requirement for high quality medical testing to provide the appropriate standard of care will outpace current clinic and laboratory-based testing approaches in some scenarios. It is therefore apparent that a different attitude to the routine availability of home testing solutions to the current status quo is required. This should be supported by a regulatory framework that encourages approaches that put the needs of patients and providers at the center and facilitates routes to finding the optimal solution. We contest that decisions on the availability of such testing should be based on factors such as what clinically significant testing is required (qualitative versus quantitative) and in what timeframe the data is required to make clinically relevant decisions. Other considerations include the continuation of testing in locations away from home, such as on vacation, ease of shipping to the testing laboratory, and that the testing is delivered in a manner which isn't cost prohibitive. Provision of testing in this manner could involve solutions such as the availability of over-the-counter testing and / or direct shipping of test materials to the patient.

Regulation: Regulatory Practice Influence

The ATA proposes that regulatory practices should not artificially disadvantage or advantage methods for providing prescribed home testing in conjunction with

telemedicine, to address unmet patient needs. Regulatory practices have demonstrated their power to negatively affect clinical outcomes, as we were able to observe in the early stages of the COVID pandemic. When the pandemic was first sweeping across the United States, patients looking to identify COVID infection or confirm the absence of infection were required to have a PCR test, which had to be ordered by a clinician and analyzed by a laboratory. Results often took a day or two to reach the patient, if not five or six, during which time the tested individuals and public health systems were left in limbo, operating on incomplete or outdated information about either personal or public risk factors.[vi] Looking beyond COVID-19, we see similar regulatory effects with sexually transmitted infections. There was a time when individuals had to come and meet with a healthcare provider before STI testing could be performed, although research suggests that personal embarrassment, provider attitudes, and concerns about confidentiality actively discourage patients from getting tested, particularly young people who are disproportionately at risk of contracting and spreading STIs.[vii]

We contend that both the invasiveness of the collection process and the complexity of post-collection processing be considered, before determining the level of regulation appropriate in a given scenario. The degree of invasiveness of patient sample collection can be considered to be:

- **Minimal:** e.g., saliva, cheek swab, anterior nares swab.
- **Moderate:** e.g., nasopharyngeal swab, finger stick (<100 µL).
- **Substantial:** e.g., oropharyngeal swab, finger stick (>100 µL).

For the complexity of post-collection processing, it is important to consider the degree to which this is performed automatically as part of the collection process or device, versus situations where these activities are largely completed by the user. This can range from:

- **No post-collection processing:** the mechanism is incorporated directly into the assay device.
- **Simple transfer:** the sample is added directly to the assay device from the collection mechanism.
- **Simple mixing:** the sample is added to a standardized buffer/Dx reagent before the entire mixture is added to the assay device, with no time or temperature constraints.
- **Complex:** the process requires some combination of filtering, multiple mixings, or timed and/or quantitative transfers post-collection.

A further consideration for the complexity of sample collection and processing is whether these operations are performed with supervision. We contend that supervision does reduce complexity with respect to the patient understanding the collection procedure, the timing and sequence of processing, and the accuracy of result interpretation. However, supervision does NOT reduce complexity with respect to any physical limitations of the end-user.

Based on the above, it is our recommendation for the purposes of setting regulatory standards that home tests be presumed to be used in an unsupervised fashion, with standards in place that drive to minimize both their invasiveness and processing complexity and test interpretation.

Reimbursement

The ATA's view on reimbursement for home testing is that it should be fair and reasonable for all home testing products prescribed by a provider for screening, diagnosis and monitoring purposes.

Testing in the home brings benefits on a number of fronts, including:

- For the consumer: Increased accessibility and convenience of testing, leading to increased effectiveness of testing and subsequent intervention.
- For the community: Reduced exposure of others to infectious diseases.
- For health-care providers: Reduced burden of in-clinic activities.

Our experiences during the COVID-19 pandemic have demonstrated that consumers can routinely perform testing unsupervised at home. Given the potential benefits that home testing can offer to consumers and the healthcare system, fair reimbursements should therefore be considered for technologies that enable testing at home and for collection devices that enable the transportation of patient specimen(s) to a laboratory.

Democratization of access to care: Low socioeconomic status is a determinant of access to health care. Persons with low incomes are more likely to be Medicaid recipients or uninsured, have poor-quality health care, and seek health care less often; when they do seek health care, it is more likely to be for an emergency. Seventy percent of today's medical decisions depend on laboratory results; but traveling to receive testing services places the burden on patients. For individuals with physical limitations, acute conditions, or low incomes, or those lacking paid time off from their jobs, backup care options for their dependents, or personal transportation, these burdens can significantly affect their ability to access healthcare services.

Nearly 80% of rural America is "medically underserved."[x] Seniors living in rural settings have fewer options for care and are often required to travel significant distances just to get the treatment they need. Compared to those living in urban areas, rural communities face higher death rates from heart disease, cancer and stroke, and are 17 percent more likely to have diabetes.[xi]

Benefit of convenience: Many studies have demonstrated that patient convenience is essential for patient compliance. The elimination of burdensome tasks lowers the inertia of a process, which is more important to patients at economic disadvantage or challenged with mobility issues. A review of geriatric patients' experience of telemedicine systems revealed that participants found telemedicine to be more convenient than a conventional visit to the doctor. Reducing the burden of scheduling and travel logistics for specimen collection can increase the likelihood of a patient to stay in monitoring compliance.[xii]

Benefit of screening: A screening test is done to detect potential health disorders or diseases in people who do not have any symptoms of disease. The goal is early detection and lifestyle changes or surveillance, to reduce the risk of disease, or to detect it early enough to treat it most effectively. For example, screening can often find colorectal cancer early, when it's small, hasn't spread, and might be easier to treat.

> *When colorectal cancer is found at an early stage before it has spread, the 5-year relative survival rate is about 90%. But only about 4 out of 10 colorectal cancers are found at this early stage. When cancer has spread outside the colon or rectum, survival rates are lower. Unfortunately, about 1 in 3 people in the US who should get tested for colorectal cancer have never been screened.*[xiii]

Benefit of monitoring: Over 154 million Americans are currently diagnosed with at least one chronic condition requiring regulatory monitoring to triage treatment and monitor disease progression.[xiv] Diseases like chronic kidney disease, diabetes, and heart failure (collectively 81M patients[xv]), disproportionately affect patients in lower socioeconomic brackets, who are least likely to have flexibility in their schedules or convenient geographic access to laboratory services.[xvi] For example, only one-tenth of patients initiating angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) therapy for heart failure, hypertension, chronic kidney disease and coronary artery disease receive the guideline-recommended creatinine monitoring. Moreover, the vast majority of the patients fulfilling post-initiation discontinuation criteria for creatinine and potassium increases continue on treatment, against clinical guidelines.[xvii]

The Centers for Medicare & Medicaid Services (CMS) already reimburse some telemedicine services. Testing is critical to inform clinical decisions, so without testing results, telehealth consultation is not as effective. Adding testing components would make telehealth consultations more effective and reduce the patient burden of coordinating visits to reference laboratories.

Access to testing for patients in rural settings, those who are non-ambulatory, and those with limited access due to limited financial resources is a known challenge to the US national health care system. Providing reimbursement for a convenient testing alternative at home can enable this access much more easily and affordably than establishing additional clinics or having to send laboratory professionals into the home. For at-home testing that is under doctor supervision (DX) for tests that are regulated by US Food and Drug Administration (FDA) or performed by a CLIA certified reference laboratory, reducing patient financial burden for at-home testing has the potential to increase screening and monitoring compliance with recommended medical guidelines.

In order to capture the full benefits both to the consumer and to the health care system of effective patient screening and monitoring, particularly for the least-served members of the community, reimbursement for at-home testing, whether a test or specimen collection device/kit to enable de-centralized testing, should be fairly reimbursed.

Home Testing Terminology

The COVID-19 pandemic has dramatically increased the incidence of testing in the home, as a result exposing the general public to an unprecedented volume and variety of medical testing information. Medical science has responded with all of its tools to the various waves of COVID infections, offering lay people a sometimes-confusing array of new options for diagnostic care.

To improve understanding and reduce confusion around the myriad of ways that tests can be performed at home, especially as telehealth supervised testing expands, the ATA Home Testing SIG has begun building a dictionary of critical terms definitions. We hope this collection of terminology can serve as a framework for alignment and discussion within the industry and for the general public. Appendix A includes the first set of terms included in this new dictionary. We have also included a list of external references that can be consulted as the authoritative sources of definitions of a far broader set of terminology put forth by the FDA, CMS and laboratory legislation. See Appendix B.

Conclusion

Testing at home, at the workplace, at school and on the road has become a new standard during the last few pandemic years, forging new processes and conventions that can and should open the door to expanded home testing across the full spectrum of telehealth addressable use cases. To fully leverage these gains, it is critical that we remember that 'Telehealth IS Health'. Providers and patients are best able to determine what venue is appropriate for home collection and/or testing. Therefore we must ensure that regulatory practices do not artificially disadvantage or advantage methods for providing Home Testing in conjunction with Telemedicine to address unmet patient needs, and that reimbursement for provider-prescribed Home Testing screening, diagnostic, and monitoring products is fair and reasonable.