U.S. Chamber of Commerce

1615 H Street, NW
Washington, DC 20062-2000
uschamber.com

Re: U.S. Chamber Comments to the International Trade Administration; Healthcare Services Sector Export Market Landscape; ITA-2021-0004; 86 FR 52635

November 8, 2021

The U.S. Chamber of Commerce welcomes the opportunity to provide the International Trade Administration with comments on request ITA-2021-0004 regarding the health care services sector export market landscape.

U.S. private sector businesses and organizations have served as key global contributors to the global health care space and have tremendous potential to expand upon current U.S. exports of health services and the health products and technologies that underpin the health care service sector. As ITA considers providing more robust support to the U.S. health services sector to increase exports, it is important to recognize the benefits of U.S. services export expansion more broadly for the American economy and people. The U.S. business services employ 20.8 million Americans, nearly 70% more Americans than those employed in manufacturing. Higher wages and productivity are also reported by U.S. companies that export their services. The U.S. is the largest exporter of services in the world, yet the trade potential of these services remains relatively limited compared to manufacturing exports. Nearly 3 million new American jobs could be created if foreign barriers to services trade were eliminated. This untapped potential of the U.S. services export sector provides the U.S. government with an opportunity to positively impact the U.S. economy.

The U.S. health care service industry is capable of rapid expansion into foreign markets due in large part to recent and ongoing technological development. Technology holds enormous benefits to enhance our ability to innovate and deliver health care both domestically and abroad. Whether applied to the research ecosystem for new medicines, the infrastructure of clinics, hospitals, and health care centers, or to the models for delivering health care information and services to both urban and rural populations, digital health technology utilization is central to the health of the world. Indeed, as the COVID-19 pandemic made clear, the increased ability to deliver many health services remotely is critical to ensuring populations continue to receive the long-term and preventative care they need. This is true not only during a pandemic, but to deliver services to underserved communities globally.

A critical component of delivering health services also includes whole health service platforms. U.S. health insurance companies have been providing access to quality healthcare to their members, wherever they are in the world, for over 100 years. Removing market access and regulatory barriers would allow them to deliver global best practices and further innovation around the globe.

As the International Trade Administration develops its strategy to support the U.S. private sector's ability to expand their health care services exports, policymakers have a critical opportunity to craft an approach that achieves the following: boosts the U.S.' digital and data-driven competitiveness, improves its attractiveness to foreign investors,

catalyzes R&D in support of public health, facilitates strong economic growth, and, most importantly, improves the lives and health of citizens around the globe. The COVID-19 pandemic demonstrates the interconnectedness of national health care systems and therefore, the need to provide adequate health services to countries with less developed health care systems to safeguard the health of U.S. citizens. As a leading pioneer in the health care services and technology space, American businesses of all sizes have the potential to fill the global health care gaps in international markets that the COVID-19 pandemic has made more apparent. This would benefit both U.S. public health and the U.S. economy, as well as public health worldwide. Please find our high-level recommendations for your consideration below.

General Recommendations

- The elimination of services trade barriers—along with the prevention of new barriers from arising—is crucial for U.S. companies to fairly compete in foreign markets, particularly in emerging markets. Therefore, trade agreements must support open investment and be backed by strong enforcement mechanisms.
- Globally, cost containment measures have become a challenge for ensuring robust and resilient health systems. While governments implement measures as a means of providing a short-term fix to budget constraints, they often overlook the broader implications on patients and health systems. It is critical for governments to formulate and implement pricing and reimbursement policies that adequately recognize the value of the therapeutic solution and support sustainable patient access to medicines.
- Ensuring the continued free flow of data, people, and goods and limiting localization requirements—including for anonymized health data— bolsters market access for U.S. companies of all sizes, which ultimately improves the competitiveness of U.S. industry and drives consumers' access to health services. We encourage ITA to work to end localization policies in foreign countries.
- Policies and regulations governing health care services can differ between markets, creating additional complexity for U.S. companies to navigate. ITA and other U.S. government agencies should continue to strive towards establishing common regulatory standards to improve predictability and interoperability. This includes the registration of new products and the renewal of existing products.
- Focus on strengthening public procurement mechanisms, so that it is a fair, transparent, and efficient process. This is a process that takes into consideration multicriteria tendering models, that considers the full range of value, that the process is predictable, that allows for physician and patient choice, and that it is not discriminatory, allowing for full consultation with stakeholders.
- Companies such as health insurers need access to a global network of hospital providers. Other healthcare service companies utilize data from many locations related to research and development. Consequently, it is critical that the international exchange of health data remain open and seamless to ensure that members take advantage of the clinical capabilities afforded to them. To support this effort, the U.S. government should work with its partners to ensure that market competition for cloud services providers remains open and robust.
- ITA should prioritize efforts that accelerate adoption of digital health tools. This should include foundational elements such as IT infrastructure investment, acceleration of digitization of health records, adoption of patient monitoring and telehealth technologies, advancement of the use of population health management tools, and facilitation of the use of digital health innovations.
- The continued protection of trade secrets and intellectual property rights, especially for data shared through the provision of health care services, will be essential to maintain a competitive environment. ITA should continue to protect the IP of U.S. private industry as the health care sector expands into foreign markets.
- State-Owned /State-Supported Entities (SOE/SSEs), as well as their subsidies, must be held to the same standards as companies operating according under market principles to ensure fair competition. Enterprises of

all types must be treated equally and subject to the same level of enforcement regarding regulation, licensing requirements and provision, transparency reporting, business operations, and procurement.
- Future trade agreement must build upon the digital provisions included in existing trade agreements, notably the USMCA and our agreement with Japan.
- Value based decision making by health authorities, which considers therapeutic benefits, quality of life benefits and socioeconomic benefits should be encouraged.

Section 1: Prospects for the Provision of International Health Care Services

- Government procurement mechanisms should be inclusive and consider a leveled, competitive landscape, which does not favor one organization or local industry and restricts other groups, such as multinational organizations.
- Some countries maintain discriminatory data localization policies that inhibit the use of health technology. Under these policies, in-country organizations must maintain their data (or sensitive data, such as health information) within the country's borders. This can restrict the use of digital health tools that store data outside the country. As a result, these data localization policies inhibit organizations from effectively leveraging data and analytic tools to improve patient, public, and population health. ITA should ensure that health care organizations can store data how and where they choose.
- COVID-19 has highlighted gaps in the ability for organizations to obtain and leverage data to understand disease spread in their communities and track disparities. Policies are needed to ensure that public health officials obtain the data they need to respond to routine and future public health threats. This must include a focus on leveraging data for population health purposes to help underserved patients and promote health equity. Similarly, any localization requirement for health care services and products limits the competitiveness of U.S. industry and patient access.
- Many countries lack the necessary foundation for digital health, notably electronic health record platforms that can seamlessly share data across patients, clinicians, researchers, and public health officials. Therefore, greater investment and clear interoperability guidelines are needed to ensure that this foundational requirement exists around the globe.

Examples of Country-specific Trade Barriers Affecting the U.S. Health Care Services Export Sector

- **Australia and New Zealand:**
  - In Australia, further regulatory alignment with the FDA would improve time to market for innovative health technologies. Additionally, current reimbursement reform may impact the adoption of more innovative technologies and timeframes for adoption. In New Zealand, procurement reform and the introduction of a new regulatory regime will likely make the ability to bring products to this market more complex.
  - ITA should work with both the Australia and New Zealand governments to address regulatory and reimbursement hurdles in the landscape, as well as potentially engaging with state-level governments on health technology.
- **Brazil:**
  - In 2010, the Brazilian government issued Federal Law 12.349/10, which provides preference to locally manufactured products and services. Several other PDP regulations have since been proposed with the request for industry input, but these new proposals continue to lack sufficient transparency for the private sector to operate fully.
- **India:**

- We have seen an increase in localization requirements from preferential treatment in government procurement systems through the Public Procurement (Preference to Make in India) Order that, for all practical purposes, prevents procurement of any product or therapy that is less than 50% localized. Increasingly, American companies are unable to compete on equal footing with Indian companies because they are disadvantaged by localization measures and preferences even though there is patient demand for the innovative treatments offered by U.S. firms.
- In recent months, there has been a significant backsliding from internationally accepted regulatory norms in India. Indian authorities require local data and studies to approve new therapies and clinical trials for the market. As a result, these new requirements are creating market access barriers for U.S. products, leading to delay or even non-availability of such proven therapies for patients in India. The continued issues of subjectivity seen in Subject Expert Committee (SEC) recommendations when it comes to waiver for Phase 3 or Phase 4. There are no standard rules being applied and outcome depends on one / two Sec exports who may be vocal.
- U.S. exporters have concerns with the recently launched Indian Certification of Medical Devices Scheme (ICMED) Plus Scheme, which diverges significantly from global norms. It runs the risk of creating additional hurdles for domestic manufacturers in India that are part of the global supply chain and seek to expand their markets globally. ICMED Plus will reduce timely access to important medical technologies, including diagnostics, when they are needed most. Compliance with a harmonized, internationally accepted standard helps Regulators expedite access to life-saving treatments because they can rely on existing ISO 13485 certificates to ensure the safe production and control of medical devices and IVDs. By introducing ICMED Plus, India is defeating the ability to rely on other trusted Regulators when medical technologies, including diagnostics are most critical and resources are most limited (e.g., during a pandemic).
- India places limits on management expenses and agent/broker commissions in their insurance market that, if modified, will promote innovation and growth in the health insurance industry and deepen penetration of healthcare coverage for all of India's consumers. At present, the insurance regulator (IRDA) imposes regulatory limitations on the amount of premiums insurers may spend on management expenses generally, and on agent/intermediary commissions specifically. The current regulatory restrictions and intensive management of expenses limit the ability of stakeholders to freely allocate expenses among the various opportunities available (including to medical management and promoting better health outcomes), discourage differentiation in the industry (which ultimately negatively impacts the choices available for the Indian consumer), and stifle technological and other innovation and investment in the Indian healthcare market.

- **Mexico:**
  - Mexico has generally abided by Chapter 13 of the USMCA, which requires goods and services to be procured through open tendering procedures. However, new proposals to amend the Procurement Law, such as claiming that "market research" provisions may exclude tenders from countries to include the U.S., brings about national treatment concerns. It is crucial that Mexico continue to commit to the open tendering under USMCA to ensure U.S. businesses operate on the same level playing field.
- **Russia:**
  - Russia engages in discriminatory practices in the state's government procurement practices. To note, the European Union submitted a consultation request in July 2021 to the WTO to meet with Russia to discuss Russian efforts to reduce EU companies' ability to sell goods and services to Russian state-owned enterprises through procurement processes.

U.S. Chamber of Commerce

1615 H Street, NW
Washington, DC 20062-2000
uschamber.com

- South Korea:
  - Several regulatory barriers exist including health technology assessment, lack of value appraisal in reimbursement determination, non-globally harmonized GMP system, requirement for biocompatibility test data, price cut investigating import prices, and reuse of single use devices.
- Vietnam:
  - Local licensing requirements and/or other certifications negatively impact U.S. exporters' ability to operate in Vietnam. For instance, health care services sold to Vietnam have to get approval from the Vietnamese government for public sector use. In comparison, for the private sector, health care services can be sold directly.

Section 2: Complementary Needs

- Countries require a trained workforce with the necessary information and computer technology skills needed to use advanced data and analytic digital tools. Specific trainings (e.g. in cloud technology) can equip their workforce with the skills needed to support the digitization of care. Furthermore, the training of international personnel is extremely important for their success in exporting health care services due to the diverse cultural and socioeconomic differences that exist between the U.S. and much of the world.
- When entering a market, exporters can directly establish representative offices or work through distributors and already established local partners to find local representatives and employees. As the medical technology market has matured, it has become less difficult for U.S. exporters to gain entry to foreign markets.

Section 3: ITA Support

- In general, government to government talk should be enhanced to influence deregulation and improve the market access environment for U.S. exporters.
- ITA should prioritize efforts that accelerate the adoption of digital health tools. ITA should assist with the transition of health records from paper to electronic formats, the adoption of remote patient monitoring and telehealth tools, the advance implementation of population health management tools, and otherwise facilitate the use of digital health innovations. To use these kinds of tools effectively, organizations must be able to store, analyze, and use data. Barriers to the use of data in the most efficient way possible will inhibit adoption of digital health tools, harming global health and US competitiveness.
- Trade shows, trade missions, and match-making are useful for the promotion of export activities.

Conclusion

The Chamber thanks the International Trade Administration for the opportunity to provide these comments and voice our support of the expansion of the U.S. health care services industry into foreign markets. Robust and sustained engagement with the business community is essential to better public health outcomes. We therefore look forward to continued dialogue on the future of U.S. health care services exports, as well as other foundational international public health policy issues.

U.S. Chamber of Commerce

1615 H Street, NW
Washington, DC 20062-2000
uschamber.com

Contact

Varnee Murugan

Senior Director, Global Initiative on Health and the Economy

US Chamber of Commerce

vmurugan@uschamber.com

Danielle Munoz

Policy and Program Manager, Global Initiative on Health and the Economy

US Chamber of Commerce

dmunoz@uschamber.com