AdvaMed
Advanced Medical Technology Association

September 15, 2025

By Electronic Submission to www.regulations.gov

The Honorable Pamela Jo Bondi
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, D.C. 20530

Re: Request for Information: State laws significantly and adversely affecting the national economy or interstate commerce (Docket No. OLP182)

Dear Attorney General Bondi:

The Advanced Medical Technology Association ("AdvaMed") appreciates this opportunity to submit the below comments in response to the U.S. Department of Justice ("DOJ") Request for Information on State Laws Having Significant Adverse Effects on the National Economy or Significant Adverse Effects on Interstate Commerce ("State Laws RFI"), published at 90 Fed. Reg. 39,427 (Aug.15, 2025).

AdvaMed is a trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members invent, develop, distribute, and manufacture much of the lifesaving and life-enhancing healthcare technology transforming healthcare through earlier disease detection, less invasive procedures, and more effective treatments.

Our members, ranging from the largest to the smallest medtech innovators and companies, help patients stay healthier for longer, recover more quickly after treatment, and improve clinicians' ability to detect diseases (including chronic diseases) earlier and treat more patients more effectively and efficiently. At the same time, the innovation and advancements in medtech driven by our members result in dramatically reduced healthcare costs.

The role of medtech in improving patient health is well-known. In the U.S., a robust innovation ecosystem for medtech exists that enhances both patient health and access to care. Indeed, the U.S. medtech industry is responsible for a highly disproportionate share of medical advances globally.[1] Yet, this medtech

[1] The United States is ranked first in various measures of healthcare innovation. *See, e.g.,* 2020 FREOPP World Index of Healthcare Innovation, ranking the United States first in Science & Technology Healthcare Innovation with a score of 75.14, well above second-place ranked Netherlands (49.97). Available at https://freopp.org/wihi2020-505b1b60bce6.

innovation ecosystem is fragile and extremely sensitive to changes in the cost of innovation, which is substantial.[2]

The fragility of the medtech innovation ecosystem results from several factors, including the extremely expensive development process from concept to product launch.[3] Numerous additional obstacles can hinder ideas and cost-saving improvements in healthcare from reaching the market to help patients effectively. In particular, the complexity arising from the over-regulation of the industry and certain regulations that are unnecessary, inconsistent with the law, overly burdensome, outdated, or unsound inhibit patient care and innovation and otherwise stifle American businesses and American ingenuity. The continued ability of medtech companies to make rapid, significant, and sometimes transformational advances in medical technology depends on a fair and reasonable regulatory system.

I. Inconsistent HCIR Credentialing Harms Patients and Interstate Commerce

A. Credentialing Requirements Patchwork: Duplicative, Costly, and Delay-Inducing

Health Care Industry Representatives ("HCIRs") are specialists from medical technology companies who provide training and technical support for medical devices used in hospitals and operating rooms ("ORs"). They are sometimes called "company representatives" or "reps" and function to help clinical teams understand how to safely and effectively use and maintain medical devices. Clinicians request HCIR to be present during surgical procedures to provide real-time technical guidance. They may need to explain how a medical technology's unique settings and technical controls function and may make recommendations. HCIRs may also calibrate devices or input settings according to the physician's specifications. For example, a representative could assist the surgical team in calibrating a laser or programming a pacemaker to the surgeon's specifications. This support helps procedures proceed efficiently and can improve patient outcomes by optimizing device performance.[4]

However, the credentialing requirements to permit HCIRs access to hospitals vary widely across the country. Each hospital may impose its own credentialing requirements (including certain background checks, drug tests, immunization proofs, training modules, and vendor-specific fees for third-party credentialing services). The proliferation of varied credentialing requirements, the lack of reciprocity between facilities, and frequent demands for "primary source" verification of documents (even when a credential had already been verified elsewhere) have resulted in highly inefficient and duplicative

[2] See National Library of Medicine, National Center for Biotechnology Information, Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report at 21, available at https://nap.nationalacademies.org/download/12960 ("The medical device innovation ecosystem is fragile and extremely sensitive to changes in the cost of innovation, which is substantial. . . The system is already under immense economic pressure).

[3] Id.

[4] Additional background on the role of HCIRs is available at https://www.advamed.org/health-care-industry-representatives-hcirs/

credentialing processes. This patchwork imposes heavy costs on the healthcare system – over $1 billion annually by one estimate – and slows the deployment of qualified industry reps who support patient care, in some cases resulting in delays to urgent care. Small businesses and new market entrants are especially disadvantaged, as they must navigate a maze of credentialing vendors and hospital-specific rules in each state before their experts can enter an operating room or other procedural area.

Beyond direct costs, these fragmented requirements create barriers to interstate commerce. A company operating nationally must ensure each of its representatives meets the idiosyncratic credentialing rules of numerous hospitals in different states, each using different platforms and standards. In practical terms, patients may face delays in care if a needed device expert cannot quickly satisfy a new hospital's unique credentialing steps. Some states have introduced legislation to establish specific HCIR credentialing requirements on a statewide level.

The credentialing systems appear to borrow from the model deployed for clinician privileging, which integrates numerous redundancies to prevent clinicians who have been disciplined or sanctioned by one institution or state board from easily moving to another hospital and repeating the same practices. Redundancies in clinician privileging are also crucial in preventing physician impersonators from participating in patient care. On the other hand, HCIRs never make medical decisions or directly provide patient care, so numerous redundant and varied credentialing requirements do not offer the same value and instead, undermine healthcare efficiency on a national scale.

The current environment has also given rise to questionable "pay-to-play" arrangements, in which medical technology companies feel pressured to pay fees to third-party credentialing or purchasing vendors in order to conduct business at certain hospitals. The HHS Office of Inspector General ("OIG") recently examined such practices. In OIG Advisory Opinion 25-04, a device manufacturer proposed paying an annual fee (~$450,000 in total) on behalf of its hospital customers to a vendor for performing required screening and compliance checks (exclusion list monitoring, etc.).[5] OIG concluded that this arrangement could violate the federal Anti-Kickback Statute, finding that it constituted improper remuneration covering a cost the hospitals would otherwise incur and raised "anti-competitive 'gatekeeper' concerns" by potentially steering business toward manufacturers willing to pay these fees. Likewise, in OIG Advisory Opinion 25-08, OIG issued an unfavorable opinion on a proposal where a medical device company would pay a third-party vendor for access to the vendor's electronic "bill-only" purchasing system used by some hospitals.[6] OIG again warned that paying to access a hospital's preferred billing/credentialing platform poses a kickback risk – effectively a fee to gain or maintain business. These opinions underscore that the current patchwork of non-standard credentialing and purchasing systems can lead to duplicative services and pay-to-play fees, which not only burden companies but also raise concerns about fraud and abuse

[5] HHS OIG, Advisory Opinion No. 25-04 (June 20, 2025), https://oig.hhs.gov/compliance/advisory-opinions/25-04/.

[6] HHS OIG, Advisory Opinion No. 25-08 (July 7, 2025), https://oig.hhs.gov/compliance/advisory-opinions/25-08/.

nationwide.

B. Proposed Federal Solution Part 1: Adopt ANSI SC 1-2020 via Medicare CoPs SOM

The Centers for Medicare & Medicaid Services ("CMS") should utilize its authority to establish a national credentialing standard that hospitals must follow as a condition of participating in Medicare, thereby effectively preempting inconsistent state, local, and institution-specific rules. AdvaMed strongly urges recognizing the current version of the **American National Standard for Supplier Credentialing in Healthcare ("ANSI SC 1-2020")**[7] [Attachment A], as satisfying the relevant elements of the CMS Medicare Conditions of Participation ("CoPs") for hospitals, 42 C.F.R. Part 482.

One way to recognize ANSI SC 1-2020 could be through a CMS update of its State Operations Manual ("SOM"), adding language in Appendix A[8] that identifies the American National Standard for Supplier Credentialing in Healthcare as an acceptable standard of practice for compliance with the applicable provisions of 42 C.F.R. Part 482.

This ANSI standard, developed through a multi-stakeholder consensus (including the FDA, hospital systems, nursing organizations, and industry), defines a comprehensive set of credentialing criteria for healthcare supplier representatives, covering background checks, immunizations, training (such as OSHA and HIPAA modules), competency attestations, and other verifications. The standard was specifically created to set a rigorous yet uniform benchmark nationwide and minimize variation in requirements. Adopting ANSI SC 1-2020 as a national credentialing standard via Medicare CoPs would mean that if a representative meets the ANSI SC 1-2020 requirements (which could be verified through a one-time, nationally recognized credential), any Medicare-participating hospital would accept it. This would immediately reduce redundant checks and costs – providers who embrace the ANSI SC 1-2020 standard help free the healthcare system from duplication of effort, redundancy of processes, and excessive labor time associated with current practices. It would also obviate the need for device companies to pay multiple third-party vendors for overlapping services that are duplicative of their own credentialing efforts, thus curtailing the pay-to-play dynamic. Notably, compliance with ANSI SC 1-2020 is currently voluntary; however, AdvaMed and other stakeholders endorse its broad adoption to enhance efficiency and compliance. Federal action to require or incentivize its adoption would amplify these benefits across all states.

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[7] ANSI/NEMA SC 1-2020, American National Standard for Supplier Credentialing in Healthcare (Oct. 15, 2020), https://c4uhc.org/wp-content/uploads/2023/07/ANSI-NEMA-SC-1-2020-AsPublished-003.pdf

[8] Centers for Medicare & Medicaid Services, State Operations Manual, Appendix A: Survey Protocol, Regulations & Interpretive Guidelines for Hospitals (CMS, [Rev. 220; April 19, 2024]), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.

C. Proposed Federal Solution Part 2: OIG Guidance and Safe Harbor for Low-Cost, Centralized Credentialing/Bill-Only Platform

The OIG and DOJ could endorse the development of a nonprofit, nationwide credentialing platform – one that charges only a nominal fee to cover costs – as an alternative means of conducting or verifying the ANSI SC 1-2020 specified credentialing elements. Such a neutral, nonprofit could operationalize the national standard into an interoperable "passport" across hospitals through a voluntary national HCIR credentialing and "bill-only" purchasing portal (potentially under the aegis of a coalition of healthcare providers and suppliers). Such a platform would allow industry reps to upload credentials once to meet the ANSI SC 1-2020 standard, and the platform could facilitate the verification of the uploaded credentials by recognized Credentials Verification Organizations ("CVO") and display when the listed CVO verified X credential, eliminating the need for re-verification by the numerous other hospitals a HCIR must support. Likewise, for "bill-only" transactions (where devices are supplied for a procedure and billed afterward), this platform could serve as a common electronic purchase order and invoicing system accessible to all participating hospitals and suppliers. Importantly, if structured as a low-cost utility, it avoids the profiteering that concerned the OIG. Hospitals and suppliers would share in the efficiencies – fewer administrative overheads for hospitals, and a single point of entry for suppliers (without hefty access fees). The Healthcare Standards Institute ("HSI") is already spearheading a related effort to develop a national "Bill Only" standard for healthcare procurement with anticipated ANSI accreditation. This standard aims to streamline the documentation and data elements required in bill-only device purchasing, reducing the current complexity and variability in these processes. We support HSI's work and believe a federally endorsed platform leveraging such standards could operationalize the concept. CMS (with input from OIG) could explore a demonstration or pilot for a unified credentialing and billing clearinghouse. Federal endorsement would send a strong signal and likely draw broad participation, given the much-needed relief from today's costly maze.

D. Agency Expertise

The above issues span healthcare regulation, the Anti-Kickback Statute/fraud & abuse, as well as competition concerns. We suggest that HHS (CMS) take the lead in setting credentialing standards via Medicare regulations (with authority under the Social Security Act to ensure health and safety in hospitals) and guidance, and on convening stakeholders for a national platform. The HHS OIG should continue to investigate and prevent abusive pay-to-play schemes, while collaborating with CMS and stakeholders to develop a national option. Meanwhile, DOJ Antitrust Division can support these efforts by highlighting how inconsistent state or institutional requirements impede competition and by being receptive to collaborations (like the proposed platform) that improve efficiency without harming competition.

E. Conclusion

AdvaMed thanks the Department of Justice for soliciting input on these critical issues. The fragmented HCIR credentialing systems and bill-only practices, even if well-intended, can impose significant nationwide burdens and costs with minimal benefit. They disrupt the fair and reasonable regulatory system necessary to sustain medical innovation, ultimately impairing patient care by diverting resources and creating barriers to patient access. We believe the proposals presented above would substantially alleviate unnecessary regulatory burdens, aligning with the Administration's deregulatory initiatives, while preserving public health and safety.

AdvaMed stands ready to work with the DOJ and relevant federal agencies to implement these recommendations. By addressing these concerns, the federal government can help ensure that states do not erect inadvertent roadblocks to the interstate flow of medical technologies that American patients depend on.

Thank you for your consideration of these comments. Please contact Terry Chang (tchang@advamed.org) for further information or collaboration.

Sincerely,
/s/
Christopher L. White
General Counsel & Chief Policy Officer
Advanced Medical Technology Association (AdvaMed)

ATTACHMENT A

ANSI/NEMA SC 1-2020

American National Standard for Supplier Credentialing in Healthcare

Secretariat:

National Electrical Manufacturers Association/MITA

Approved: October 15, 2020

American National Standards Institute, Inc.

ATTACHMENT A

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Foreword (This foreword is not part of American National Standard NEMA SC 1-2018.)

This Standard has been developed to describe requirements for supplier credentialing in a healthcare environment.

Patient safety and privacy and security of patient data are of utmost importance to providers and suppliers in the healthcare industry. Many suppliers review their representative's qualifications and readiness to support healthcare providers via:

a. Criminal Background Checks (including sanction list checks)
b. Medical Testing/Vaccinations
c. Drug Screens
d. Applicable Training

There are some accreditation organizations' Standards that apply to all individuals in a healthcare provider facility. However, because there are currently no national Standards, laws, or regulations, healthcare providers have their own requirements and processes. As a result, to credential their employees (supplier representatives), Suppliers shall engage in duplicative efforts with no tangible benefit and at a high cost to the United States healthcare system. In addition, supplier representatives may be subjected to equal or sometimes greater scrutiny than healthcare provider employees, even though supplier representatives have minimal to no direct contact with patients. Moreover, suppliers and supplier representatives are often required to send sensitive personal data to many third parties.

A single set of credentialing Standards and an interoperable process to verify those credentials in real time will address healthcare provider and supplier concerns for patient safety, supplier representative privacy, and data security while eliminating significant cost and wasted effort from the healthcare industry. These resources can be better utilized by providing improved products and services.

In the fall of 2017, the Consortium for Universal Healthcare Credentialing (C4UHC) began efforts to create certified ANSI Standards for credentialing requirements and processes. Consistent with ANSI requirements, a diverse cross-section of all relevant collaborators was convened to participate to ensure the Standards meet all relevant stakeholder concerns with fair balance and transparency.

These Standards were created to help address the concerns of the current credentialing process with the goals to mitigate risk, increase accuracy and efficiency, and reduce unnecessary costs for the U.S. healthcare system and its patients.

This Standard was updated in the summer of 2020 to address new supplier credentialing challenges which emerged as a result of the COVID-19 pandemic. NEMA SC 1-2020 revises and supersedes NEMA SC 1-2019. A reasonable grace period for implementation of the ANSI Standards shall be granted to suppliers and supplier representatives.

This Standard was prepared by the National Electrical Manufacturers Association's MITA ANSI Canvass Body, Supplier Credentialing (SC 1). The Standard will be reviewed for revisions periodically. Suggestions for improvement of this Standard will be welcome. They should be sent to the National Electrical Manufacturers Association, 1300 North 17th Street, Suite 900, Rosslyn, VA 22209.

This Standard was processed and approved for submittal to ANSI by the National Electrical Manufacturers Association's MITA ANSI Canvass Body, Supplier Credentialing (SC 1). Committee approval of the Standard does not necessarily imply that all committee Members voted for its approval. At the time of its approval, the SC 1 Committee had the following Members:

Rhett Suhre, Chair, SC1 Committee
Jan Trapp, Chair, Editorial Team
Lori Russell, Editor
Peter Weems, Secretary

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1 Scope

This Standard identifies the credentials of supplier employees (identified as supplier representatives) entering a healthcare provider facility.

Requirements are intended for supplier representatives but could be applied to other non-employees if a healthcare provider chooses to do so (e.g., independent consultants, construction contractors, and temporary personnel.) As ANSI Standards are voluntary, healthcare providers can opt in or out of enforcing any individual requirements.

Where required, these are the recommendations for the specific requirements.

Requirements are not intended for the healthcare provider staff/employees or patient/family visitors.

Supplier representative data shall be handled in accordance with applicable laws and with the same care as privacy information for patients, healthcare provider staff/employees, and other affected parties. The documentation and data indicating compliance to the Standard should remain with the responsible and accountable party but available for audit purposes.

For specific recommendations on what requirement applies to which access tier, refer to the non-employee decision matrix—see Appendix A.

Healthcare providers will define the process for validation of requirements outlined within this document and conforming to applicable laws.

For information on Independent supplier representatives, see Appendix B.

Recommend that an audit process shall be in place to verify the accuracy of data.

If for any reason a supplier representative has a legal name change, this shall be noted on the verification letter by putting the alias (former name) in parenthesis next to the current name, e.g., first name last name (nickname) [alias].

2 Definitions

2.1 **Continual:** Documented on an ongoing basis and current as of date of access

2.2 **Contracted Services:** Services provided to a healthcare provider through a written agreement with another organization, agency, or person. The agreement specifies the services or personnel to be provided on behalf of the applicant organizations and the fees to provide these services or personnel.

2.3 **FEIN:** Federal Employer Identification Number

2.4 **Healthcare Provider (HCO):** Term is inclusive of facilities providing healthcare or in the business of healthcare.

2.5 **Non-supplier Representative:** Any other individual in a healthcare provider facility who does not meet the definition of supplier representative.

2.6 **Patient Care Space:** Any space of a health care facility wherein patients are intended to be examined or treated. *Source: NFPA 99-2021, Section 3.3.140*

2.7 **Provider Facility:** Physical location of a healthcare provider.

2.8 **Remote Supplier Representative:** A supplier representative who is not required to be physically present in the healthcare provider facility but provides a service to a healthcare provider (e.g., technical support who may have access to PHI).

2.9 **Supplier:** The supplier company that provides or sells goods or services to a healthcare provider.

2.10 **Supplier Representative:** Individual who provides or sells goods or services for the supplier. These individuals are not employees of the healthcare provider.

2.11 **Vendor Credentialing Organization (VCO):** Third-party company contracted with a healthcare provider to manage the credentialing of its suppliers.

3 References

3.1 The Joint Commission

3.1.1 The Joint Commission FAQ April 2016
https://www.jointcommission.org/standardsinformation/jcfaqdetails.aspx?StandardsFAQId=908

3.2 AORN

3.2.1 AORN Guidelines for Supplier Representatives https://www.aorn.org/-/media/aorn/guidelines/position-statements/posstat-personnel-health-care-reps.pdf

3.2.2 AORN Aseptic Technique Guidelines
https://aornguidelines.org/guidelines/content?sectionid=173717350&view=book

3.2.3 Re-Entry Guidance for Health Care Facilities and Medical Device Representatives

https://www.aorn.org/Guidelines/AORN-Support/Re-entry-Guidance-for-Health-Care-Facilities

3.3 Centers for Disease Control

3.3.1 Hepatitis B Vaccination Information https://www.cdc.gov/vaccines/vpd/hepb/public/index.html

3.3.2 Influenza Seasonal Prevention and Control Information
https://www.cdc.gov/flu/healthcareworkers.htm

3.3.3 Measles, Mumps, and Rubella (MMR) Vaccination Information
https://www.cdc.gov/vaccines/vpd/mmr/hcp/index.html

3.3.4 TDAP Vaccination Information
https://www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.html

3.3.5 Tuberculosis Testing
https://www.cdc.gov/tb/topic/testing/healthcareworkers.html

3.3.6 Varicella Vaccination Information https://www.cdc.gov/chickenpox/vaccination.html

3.4 Occupational Safety and Health Administration (OSHA)

3.4.1 Bloodborne Pathogens Standard
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

3.4.2 Fire Safety
https://www.osha.gov/SLTC/firesafety/standards.html

3.5 Social Security Administration

3.5.1 https://www.ssa.gov/dataexchange/request_dmf.html

3.6 Specific to Background Checks

3.6.1 National Sex Offender Public Website
https://www.nsopw.gov

3.6.2 Office of Inspector General (OIG)
https://oig.hhs.gov/about-oig/about-us/index.asp

3.6.3 General Services Administration SAM
https://sam.gov/SAM/

4 Administrative Requirements

Administrative requirements are generally related to the individual's identification, contact information, and certain requirements generally met as part of the employment process. Certain management and company level information is also part of the administrative Standards.

4.1 Supplier Representative Data

Following are the data field Standards for collecting supplier representative data:

a. Employee Unique ID
b. Access Tier
c. First Name (Given Name)
d. Preferred Name (Nickname)
e. Middle Name or Candidate doesn't have one
f. Last Name (Family Name)
g. Generation (Jr, Sr, II, III…)
h. Former Name [Alias]
i. Parent Company FEIN
j. Date of Hire
k. Office Phone/Cell
l. Office Email
m. Job Title
n. Division Name
o. Manager First Name
p. Manager Last Name
q. Manager/Division Email
r. Badge Photo

4.2 Access Tier Level Classifications

Institutions should adopt clearly defined access tiers to support appropriate credentialing requirements.

Following are sample access tiers and sample definitions for each:

a. **Access Tier 1**: Defined as areas where no permissions or instructions beyond those required for all visitors are needed for non-employee or a supplier representative beyond a sign-in.
    1. E.g., administrative offices
b. **Access Tier 2**: Defined as areas where supplier representative or non-employee access requires healthcare provider permission.
    1. E.g., patient areas, not sterile or restricted
c. **Access Tier 3**: Defined as sterile or restricted areas where non-employee access is allowed, but supplier representative or non-employee is required to have specific healthcare provider permission and may require oversight by the medical staff and administration.
    1. E.g., Procedural patient care spaces such as operating rooms or catheterization labs

For specific recommendations on what requirement applies to which access tier, refer to the non-employee decision matrix—see Appendix A

4.3 Employee Verification

Verification of employment eligibility shall be conducted (e.g., USCIS I-9, E-Verify or other methodology)

Acceptable data specification from supplier representative:

a. Complete

4.4 Photo

A digital photo of the supplier representative shall be required for proof of identity to compare to a government-issued photo identification, e.g., driver's license, military identification, passport may be

presented at provider facility check-in, however the healthcare provider shall not make a photocopy or hold during the supplier representatives visit.

Acceptable data specification from supplier representative:

a. Professional style passport photo from a retailer or similar photo style assuring the following:
    1. Center head within the frame, face forward, eyes open
    2. Against a white, light, plain background
    3. No hats, sunglasses, or anything that obscures a full view of the face
b. JPG Format

4.5 Background Check and Drug Screen

Background check and drug screen shall be conducted by a qualified third-party screening company.

Acceptable data specification from supplier representative:

a. Date of completion and acceptance by a supplier's human resources system

4.5.1 Identity Verification

Verification that the Social Security Number (SSN) has been validly issued for the supplier representative's name and that the number is not on the "Social Security Death Master File (DMF) Index." If search results indicate that the number is invalid or no record is found, then obtain confirmation that the SSN has been recently issued and that the issue date, place, and name match the supplier representative's state history. Use an alternative method to verify that the SSN matches the subject. Identity verification consists of the registered name with a Vendor Credentialing Organization (VCO) account and legal name. A SSN trace is an additional option for identity verification.

4.5.2 Name and Address History Search

Determine the names and addresses associated with a supplier representative using a commercial database product. If no results are found, use alternative methods, to the extent available, to identify the name and address history of the subject.

4.5.3 Criminal Searches

4.5.3.1 County-, Metropolitan-Area-, or Municipal-Level Search

Use all names and addresses on the supplier representative revealed in the "Name and Address History Search" for the past seven years and those provided by the subject of the search, to determine the jurisdictions to search. Searches shall be performed directly through each county courthouse or equivalent and not through alternatives. Searches shall include misdemeanor and felony level convictions and pending cases for a maximum of 10 years (if allowable) from the date of conviction or release, whichever is the latter. If the subject has lived outside the U.S., searches of such foreign courts or their equivalent shall be completed, where available.

4.5.3.2 Statewide Level Search (if mandated or applicable)

Utilize all names and addresses on the supplier representative revealed in the "Name and Address History Search" for the past seven years, as well as those provided by the subject of the search, to determine the jurisdictions to search. Searches shall be performed directly through each state repository and not through alternatives. Searches shall include misdemeanor and felony level convictions and pending cases for a maximum of 10 years (if allowable) from the date of conviction or release, whichever is the latter

4.5.3.3 Federal Level Search

Utilize all names and addresses on the subject revealed in the "Name and Address History Search" for the past seven years, as well as those provided by the subject of the search, to determine the jurisdictions to search. Consumer Reporting Agencies (CRAs) shall conduct a search of records at each federal courthouse or equivalent for federal convictions and not through alternatives. Searches shall include felony level convictions and pending cases for a maximum of 10 years (if allowable) from the date of conviction or release, whichever is the latter.

4.5.3.4 National Criminal Database Records Search

Shall search current and historical records on individuals by accessing critical information combined from data sources and participating jurisdictions in a commercially available, nationwide criminal records database. This multi-jurisdictional search shall include aggregated criminal records, state departments of corrections, as well as any additional data sources that may be available. Any records found shall be verified at the source of information.

4.6 U.S. Department of Justice (DOJ) National Sex Offender Public Website (NSOPW) Search

NSOPW provides information regarding the presence or location of offenders who, in most cases, have been convicted of sexually violent offenses against adults and children and certain sexual contact and other crimes against victims who are minors.

Search results shall be verified by visiting the providing jurisdiction's public registry website.

4.7 Healthcare Sanctions Checks Items

Healthcare sanctions checks will verify that the supplier representative does not appear in any of the following databases:

4.7.1 Office of Inspector General (OIG) U.S. Department of Health & Human Services (HHS) Exclusion List Check

A check of the OIG List of Excluded Individuals/Entities (LEIE), which provides information to the health care industry, patients, and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid, and all other Federal healthcare programs. Individuals and entities who have been reinstated are removed from the LEIE.

4.7.2 General Services Administration's (GSA) System for Award Management (SAM) Check

This check contains the publicly available data for all active exclusion records entered by the Federal government identifying those parties excluded from receiving Federal contracts, certain subcontracts, and certain types of Federal financial and non-financial assistance and benefits. It includes:

a. Central Contractor Registry

b. Federal Agency Registration (Fedreg)

c. Online Representations and Certifications Application

d. Excluded Parties List System (EPLS)

4.7.3 U.S. Food and Drug Administration (FDA) Debarment List Check

A check of the FDA Office of Enforcement debarment list. The authority of the FDA to debar people from the drug industry comes from the Generic Drug Enforcement Act of 1992, often called the "debarment act" because it authorizes, and sometimes even requires, FDA to forbid people (or firms) convicted of certain crimes related to the government's regulation of drugs—from participating in the drug industry.

4.7.4 Global Sanction Search

To include U.S. Office of Foreign Asset Controlled (OFAC) Specially Designated Nationals List (SDN) and World Bank Checks

4.8 Employment Verification

Verification of employment is as attested by the supplier representative. This verification is expected to be completed by a supplier representative's employer at pre-employment.

4.9 Education Verification

Verification of highest level of education attained by supplier representative as attested by the supplier representative. This verification is expected to be completed by a supplier representative's employer at pre-employment.

4.10 Refresh Background Check—Essential Elements to Be Repeated Every Five Years Are:

a. Name and Address History Search
b. County-Level Search
c. Federal Criminal Records Search
d. National Criminal Database Records Search
e. DOJ National Sex Offender Public Website (NSOPW) Search
f. Healthcare Sanctions Check Items:
    1. OIG HHS Exclusion List Check
    2. The GSA System for Award Management (SAM) Check
    3. FDA Debarment List Check
    4. Global Sanction Search

4.11 Refresh Healthcare Sanctions Check—Essential elements to Be Repeated at a Minimum Every Year:

a. OIG HHS Exclusion List Check
b. The GSA System for Award Management (SAM) Check
c. FDA Debarment List Check
d. Global Sanction Search

4.12 Drug Screen

The following recommended thresholds meet or exceed common industry guidelines and shall be used for all supplier representatives' drug screens:

Drug Class	Common Detected Components	ANSI Standard Screening/Confirmation Threshold
Amphetamines	Amphetamine Methamphetamine	500/250
Barbiturates	Amobarbital Butalbital Pentobarbital Phenobarbital Secobarbital	300/200
Benzodiazepines	Alprazolam metabolite Midazolam metabolite Nordiazepam Oxazepam Temazepam Triazolam metabolite	300/200
Cocaine Metabolites	Benzoylecgonine	150/100
Hydrocodone/Hydromorphone	Hydrocodone Hydromorphone	300/100
Marijuana Metabolites	THC	50/15
Methadone	Methadone	300/200
Opiates	Codeine Morphine	2000/2000

Oxycodones	Oxycodone Oxymorphone	100/100
Phencyclidine (PCP)	Phencyclidine (PCP)	25/25

Frequency: Once

The following drugs no longer need to be included in drug screen testing as their use and incidents of positive tests are statistically insignificant.

a. Methaqualone
b. Propoxyphene

Chain of custody protocol should be followed and include appropriate ranges for the following:

a. Temperature
b. Creatinine
c. pH

5 Training Requirements

Training requirements, including safety training, product training, and compliance training, are either required by law, regulation, or deemed relevant for the supplier representative's role in a healthcare environment. The completion of these requirements is the responsibility of the supplier representatives.

Acceptable data specification from supplier representative:

a. The date the training topic has been completed and entered into the system of record.

5.1 Aseptic Technique

The supplier representative shall be trained on, and is required to follow, aseptic technique training, per the Association of periOperative Registered Nurses (AORN) guidelines.

Frequency: Once

5.2 Bloodborne Pathogens

The supplier representative shall comply with the bloodborne pathogens training, per the Occupational Safety and Health Administration (OSHA) required annually with competency assessment as attested by the supplier representative’s employer.

Frequency: Annual

5.3 Electrical Safety/Awareness

If applicable, the supplier representative shall complete electrical safety training.

Frequency: Once

5.4 Ethics and Code of Conduct Policies and Procedures

A letter from the employer verifying training and/or stating that the supplier requires the supplier representative to be trained on policies and procedures consistent with a nationally recognized applicable industry code of ethics such as the AdvaMed code of ethics or the PhRMA code of ethics.

Frequency: Annual

5.5 Fire Safety/Awareness

The supplier representative shall defer to healthcare provider employees for fire safety protocols and instructions beyond general awareness. The supplier representative is not required to train on fire safety protocols for individual healthcare facilities. If applicable, supplier representatives shall be trained and/or have a general understanding of OSHA fire safety Standards in the event of a fire. It is the responsibility of the supplier representative’s employer to train the supplier representative on OSHA fire safety Standards.

Frequency: Once

5.6 Handwashing Technique

The supplier representative shall adhere to handwashing guidelines as posted in healthcare facilities.

5.7 Health Insurance Portability and Accountability Act (HIPAA)

The supplier representatives shall complete federal HIPAA privacy and security training on an annual basis. Reoccurring annual HIPAA training is required to ensure that supplier representatives are up to date with the latest regulatory changes. Any supplemental state-regulated HIPAA privacy and security regulation training will be the responsibility of the healthcare provider Facility to facilitate and oversee that additional requirements have been completed.

Frequency: Annual

5.8 Operating Room Protocol (Sterile/Aseptic Technique)

The supplier representative shall be trained on and is required to follow operating room protocols (sterile/aseptic controls), per the Association of periOperative Registered Nurses (AORN) guidelines.

Frequency: Once

5.9 Product Complaints and Medical Device Reporting

The supplier and supplier representative are responsible for fulfilling this requirement and ensuring supplier representatives are duly trained per FDA requirements and guidelines.

Frequency: Once

5.10 Product/Service Competency

The supplier representative's employer shall provide documentation as to competency training in the form of a memo or other documents.

Frequency: Continual

5.11 Radiation Safety

5.11.1 Radiation Safety Training

If applicable, supplier representatives shall complete radiation safety training in accordance with federal and state regulations.

Frequency: Every three years

5.11.2 Radiation Dosimetry Monitoring

Shall be required if supplier representative while at the healthcare provider facility is in an area (same room) while ionizing radiation equipment (e.g., x-ray machine, CT scanner) is being used or if supplier representative is directly handling radioactive material.

Frequency: Annual

6 Medical Surveillance Requirements

Medical surveillance requirements are to promote health and wellness for all parties and is either required by law, regulation, or is deemed relevant for the role that the supplier representative performs in a healthcare environment. The completion of these requirements is the responsibility of the supplier representative. Since protected health information (PHI) is involved, additional considerations for data security and privacy are necessary.

6.1 General

The following requirements are listed in frequency order and are based on the CDC guidelines. Vaccination records and/or lab reports shall include the supplier representatives' full name, the clinic name, and contact information for verification, vaccination dates, and/or lab results. Sample Medical Verification Form—Appendix B

If a supplier representative declines a vaccination(s) that afford immunity, the healthcare provider may restrict or decline access. A temporary exclusion may be allowed if there is a note from a physician; however, the healthcare provider may still restrict or decline access. See additional declination specifics below.

6.2 Tuberculosis (TB) Testing

The supplier representative shall have TB/tuberculosis testing with non-active results.

Acceptable data specification from supplier representative with a negative TB test result:

a. Date of baseline or most recent testing via:
    1. PPD TB Skin Test
    2. TB Blood Test
b. Date of last annual TB symptom screen

In cases of supplier representative with latent (non-active) TB:

a. Date of most recent chest x-ray
b. Date of last TB symptom screen

Frequency:

Testing: Once at pre-hire, or when supplier credentialing is initially required, and in the event of known exposure or if the employee has symptoms.

TB symptom screen: annual

Chest x-ray: once at diagnosis and in the event of symptoms

6.3 Influenza Vaccination

The supplier representative shall demonstrate vaccination against influenza for the current flu season. Declination of influenza may require additional procedures per healthcare "providers" guidelines.

Acceptable data specification from supplier representative:

a. Date of vaccination

Frequency: Annual/Seasonal

6.4 Tetanus, Diphtheria, and Pertussis (TDaP) Vaccination

The supplier representative shall demonstrate vaccination against TDaP. Note: DTaP is not acceptable

Acceptable data specification from supplier representative:

a. Date of vaccination

Frequency: Every 10 years

6.5 Measles, Mumps, Rubella (MMR) Testing/Vaccination Series

The supplier representative shall demonstrate immunity against MMR.

Acceptable data specification from supplier representative:

a. Date of titer showing immunity or
b. Dates of shot series as per CDC guidelines

Frequency: Once

6.6 Varicella (Chicken Pox) Testing/Vaccination Series

The supplier representative shall demonstrate immunity against Varicella.

Acceptable data specification from supplier representative:

a. Date of titer showing immunity or
b. Dates of shot series as per CDC guidelines

Frequency: Once

6.7 Hepatitis B Testing/Vaccination Series

The supplier representative shall demonstrate reactive for Hepatitis B. A declination of vaccination can be submitted if already vaccinated but still showing reactive.

Acceptable data specification from supplier representative:

a. Date of titer showing immunity or
b. Dates of shot series as per CDC guidelines

Frequency: Once

6.8 Novel Viruses/Communicable Illness

There may be situations where there is not a vaccination or definitive test for immunity for a new or actively spreading communicable medical condition. In those situations:

a. The supplier representative entering all areas shall be screened for general wellness, exposure, and specific symptoms as recommended by CDC in the same manner as staff, patients, and patient visitors.
b. The supplier representative entering all areas of the facility shall take safety precautions against transmission in accordance with CDC community recommendations both to protect the individual and others in the facility.

Acceptable data specification from supplier representative:

a. Attestation from Supplier Representative

Frequency: Continual

Once FDA approves or CDC recommends a method for documenting immunity or vaccination is available, these Standards should be revised to reflect the documentation vs. wellness screening.

7 Personal Protective Equipment (PPE)

7.1 General Requirements

a. For Tier 1 access, the supplier representative shall comply with all requirements for protective equipment as applicable to all patients, visitors, and staff (e.g., face coverings). Requirements can be satisfied with vendor-supplied PPE.
b. For Tier 2 and 3 access, the facility shall determine appropriate PPE requirements, consistent with CDC, OSHA, and other applicable governmental guidelines, and provide such PPE for all personnel (including supplier representatives).

7.2 Close-fitting respirators and fit testing (e.g., N95 respirators)

a. Requirements for filtering facepiece respirators shall be consistent with CDC and OSHA guidelines
b. Requirements for fit testing shall be limited to those supplier representatives involved in activities or procedures for which CDC has recommended fit-tested respirators, and the facility shall provide the PPE.
c. Provisions for the use of vendor-supplied PPE in emergency situations shall follow current and applicable CDC, OSHA, and other governmental guidelines, including fit testing at the point of use.

8 Healthcare Provider Policies

Any policy that the supplier representative is asked to acknowledge acceptance by the healthcare provider should be applicable for their role. The supplier representatives shall not be required to sign documents that require an authorized representative of the supplier to sign.

9 Company Credentialing

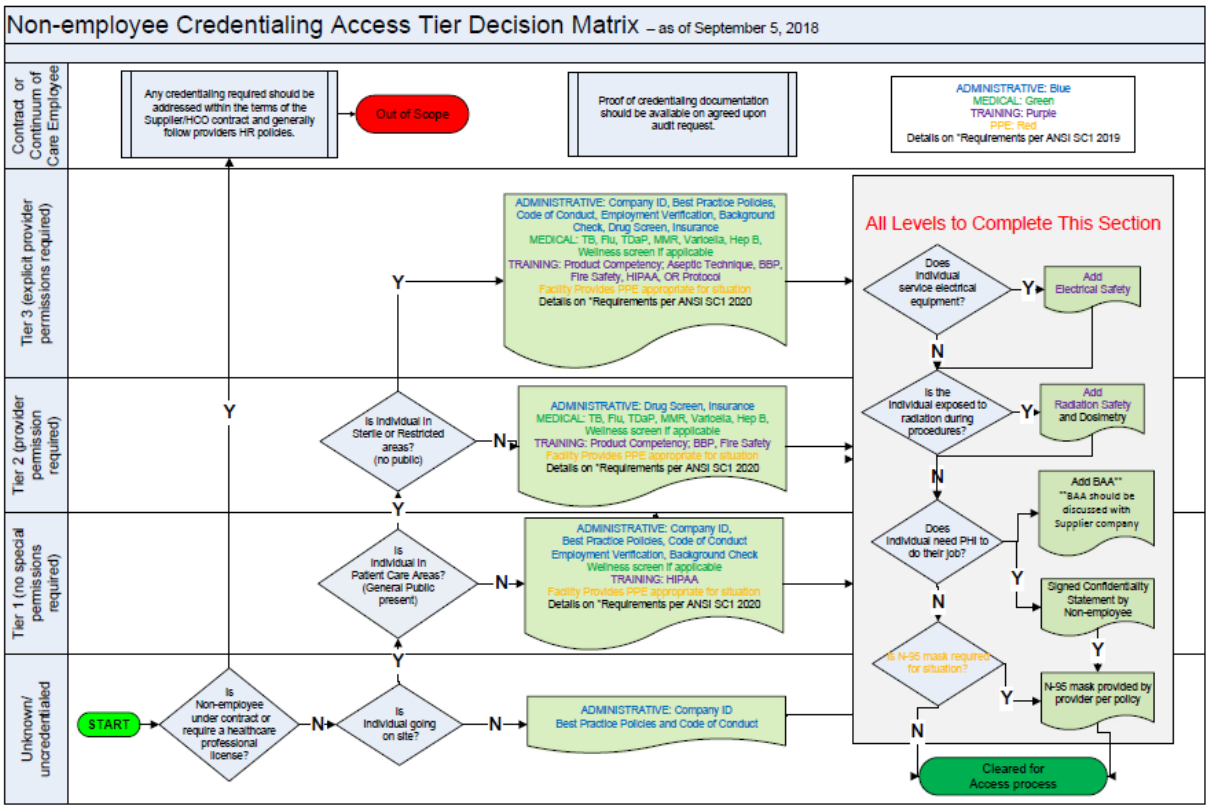
Healthcare providers often need information regarding the supplier. This is public information and shall be provided by an authorized individual of the supplier to a vendor credentialing organization or a healthcare provider.

The data elements are listed in Appendix D.

10 Business Associate Agreement (BAA)

If the supplier representative requires and/or accesses PHI to do their job and meets the HIPAA definition of” ““business associate””,” a BAA will be signed by an authorized representative of the supplier.

Appendix A
Normative
Non-Employee Decision Matrix



Appendix B
Normative

1099 Independent Contractor

1099 Independent Contractor is to comply with the SC 1 Credentialing requirements for the appropriate Access Tier as well as the following:

a. Statement of Self-Employed Status
b. Letters of Compliance
    1. Lists the suppliers represented by the Independent 1099 Supplier Representative
    2. Lists the products/services is he/she authorized to sell or service
        a. Product/Service Competency
a. Product Liability Insurance
b. General Liability Insurance
c. Product Liability Statement

Appendix C
Informative

Company Credentialing Requirements

a. Parent Company FEIN
b. Federal Tax Classification
c. Company Name
d. DBA/Disregarded Entity(is) Name(s)
e. Year Established
f. State of Incorporation
g. Physical Business Address
h. Company Web Address
i. Business Type
j. Business Sub Category
k. Publicly Traded DUN and Bradstreet Number Stock Ticker Symbol (if applicable)
l. Diversity Ownership Type (if applicable)
m. Contact
n. W9
o. I-9 Employment Eligibility Verification
p. AATB Tissue Bank Certification (if applicable)
q. Performance Review Conducted Statement
r. Remit to Contact and Address
s. Product Liability Insurance
t. General Liability Insurance
u. Aggregate Coverage Amounts
v. CEO Name and Designated Contact Email
w. CFO Name and Designated Contact Email
x. Compliance Officer Name and Contact Email
y. Credentialing Contact Name and Contact Email
z. Is your business Non-Profit
aa. Privacy Statement

Appendix D
Informative

Requirements that are not deemed appropriate for Supplier Representatives.

a. Basic Life Saving
b. Job Description/Function
c. Medicare Parts C&D Training
d. National Patient Safety
e. Performance Reviews
f. Product Type
g. Respiratory Mask Fit Testing

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