

Bobby Jindal
GOVERNOR



Bruce D. Greenstein
SECRETARY

State of Louisiana
Department of Health and Hospitals
Office of the Secretary

January 28, 2011

The Honorable Joel T. Chaisson, II, President
Louisiana State Senate
P.O. Box 94183, Capitol Station
Baton Rouge, LA 70804-9183

The Honorable Jim Tucker, Speaker
Louisiana State House of Representatives
P.O. Box 94062, Capitol Station
Baton Rouge, LA 70804-9062

The Honorable Kay Katz, Chairwoman
House Health and Welfare Committee
Louisiana State House of Representatives
P.O. Box 44486, Capitol Station
Baton Rouge, LA 70804-4486

The Honorable Willie L. Mount, Chairwoman
Senate Health and Welfare Committee
Louisiana State Senate
P.O. Box 94183, Capitol Station
Baton Rouge, LA 70804-9183

The Honorable John Schroder
Louisiana State House of Representatives
222 North Vermont Street, Suite K & M
Covington, LA 70433

Dear President Chaisson, Speaker Tucker, Representative Schroder, and Honorable Chairs:

In response to House Resolution No. 150 (HR 150) of the 2010 Regular Session, the Louisiana Department of Health and Hospitals (DHH) submits the enclosed report. HR 150 created the Medical Vendor Credentialing Task Force within DHH, whose charge was to study and analysis and to make recommendations for the establishment of a uniform and reciprocal medical vendor credentialing system. This resolution required the task force to compile the results and any recommendations to be reported to the House and Senate Health and Welfare Committees and the member representing House of Representatives' District Number 77. The R.S. 24:772 also requires that the report be submitted to the President of the Senate and the Speaker of the House.

Erin Rabalais is available to discuss the enclosed report and recommendations with you at your convenience. Please contact her at (225) 342-4997 or Erin.Rabalais@la.gov with any questions or comments you may have.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce D. Greenstein".

Bruce D. Greenstein
Secretary

Enclosures

Cc: The Honorable Members of the House Health and Welfare Committee
The Honorable Members of the Senate Health and Welfare Committee
Representative John Schroder
David R. Poynter Legislative Research Library

MEDICAL VENDOR CREDENTIALING TASK FORCE

REPORT PREPARED IN RESPONSE TO HR 150
OF THE 2010 REGULAR SESSION

JANUARY 2011

Contact:

Louisiana Department of Health and Hospitals
Erin Rabalais, RN
Office of Medical Vendor Administration
P.O. Box 3767 Baton Rouge, LA 70821
225-342-4997
Erin.rabalais@la.gov

EXECUTIVE SUMMARY

HR 150 of the 2010 Legislative Session urged and requested the Department of Health and Hospitals to create a Medical Vendor Credentialing Task Force to study the current medical vendor credentialing process, the make recommendations for the establishment of a uniform and reciprocal system of vendor credentialing, and to submit a report containing the results of the study and any recommendations.

REPORT TO THE LEGISLATURE

MEDICAL VENDOR CREDENTIALING TASK FORCE

CHARGE & COMPOSITION OF TASK FORCE

During the 2010 Regular Session of the Louisiana Legislature, the House of Representatives of the Legislature of Louisiana did urge and request the Department of Health and Hospitals through House Resolution 150 to create a Medical Vendor Credentialing Task Force (hereafter referred to as task force) to undertake all necessary actions to study, analyze and make recommendations for the establishment of a uniform and reciprocal medical vendor credentialing system for the state of Louisiana's inpatient and outpatient health care facilities (excluding physician offices and facilities not accredited to accept Medicare/Medicaid patients). Specifically, the task force was charged with making recommendations that may include but were not limited to the following:

- (1) Requirements of the vendor to receive uniform and reciprocal credentialing, such as receipt of appropriate health vaccinations, background screenings, proof of liability insurance, and the completion of training in appropriate health care law and hospital protocol.
- (2) Suggestions for the amount of fees appropriate to accomplish uniform and reciprocal credentialing.
- (3) Recommendations as to which entity would be responsible for the oversight and implementation of a uniform vendor credentialing system.
- (4) Any necessary new statutes or rules that must be promulgated in order to create a new medical vendor credentialing system.

The task force was staffed by the Department of Health and Hospitals (Omar Khalid & Brandy Hamilton) and composed of seven members appointed by the secretary consisting of:

1. Rebecca D. Bradley, Louisiana Hospital Association – Chair
2. Greg Blaum, USMedProviders – Vice Chair
3. Kendall A. Johnson, Baton Rouge General Medical Center
4. Erin Rabalais, Department of Health and Hospitals
5. Dr. Rodney Wise, Department of Health and Hospitals
6. Dr. Roxane A. Townsend, LSU Health Care Services
7. Jonathan Burkett, Acclarent

The task force has convened for five meetings and this report is a product of the discussion and research performed by the task force members.

BACKGROUND

The task force started the discussion around the state of Louisiana's role in enforcing uniform standards of medical vendor credentialing by defining guiding facts and principals. These included the following:

- The 2010 Louisiana Legislature a bill had been introduced to require state enforcement of standards; this bill was ultimately transitioned into a House Study Resolution mandating this report.
- The Joint Commission, an independent, not-for-profit organization that accredits and certifies more than 18,000 health care organizations and programs throughout the United States did review the implementation of a single standard approximately two years prior to the passage Louisiana's resolution leading to this report, but stopped short of formally proposing any standards. The Joint Commission issued the statement that they are not in the business of developing standards of competence for health care industry representatives. However, the

Joint Commission does have a number of standards that are relevant to any individual that enters a health care organization who directly impacts the quality and safety of patient care. Included in these standards are:

- Standard EC.02.01.01, which states that in order to protect patient safety, accredited health organizations need to be aware of who is entering their organization and what these individuals are doing in their organization.
 - Standard RI.01.01.01, which states that accredited health care organizations need to take steps to ensure patient rights are respected.
 - Standard IC.02.01.01, which states that accredited health care organizations need to take steps to ensure that infection control precautions are followed.
 - Standard HR.01.02.05, which states that accredited health care organizations confirms that nonemployees who are brought into the hospital by a licensed independent practitioner to provide care, treatment or services have the same qualifications and competencies required of employed individuals performing the same or similar services at the hospital.
- Currently no other states in the nation have addressed the medical vendor and credentialing industry through legislation or rule making. In addition, no national standard currently exists for health care industry representative credentialing.
 - The primary focus and consideration of the task force should be on patient safety, risk management, privacy protection and regulatory requirements.
 - The efforts of this task force aim to provide the appropriate balance among the goals of patient safety, patient and health care industry representative's privacy, high quality health care, immediate access to clinical technology, efficient communication by provider institutions and vendors with appropriate legal boundaries.

In addition it has been determined that the hospitals in Louisiana approach the credentialing of health care industry representatives in various fashions. Some health care organizations choose to keep the credentialing services within the facility and employ staff to conduct source verification of information presented by health care industry representatives before access will be granted to the facility. Other health care organizations have opted to outsource the process of health care industry representative credentialing and employ one of the private industry vendor credentialing firms that exist in the market place. These firms often times will deploy, at no cost to the health care facility, a method of electronically recording the health care industry representative's access and purpose for entering the facility thus providing additional security measures and higher levels of patient protection.

Similar to conducting physician credentialing, the activity of credentialing health care industry representatives is in no way meant to be a profitable venture for the health care facilities. Instead, it is an activity that is initiated to satisfy regulatory requirements and to ensure patient safety.

NEXT STEPS

Although the vendor community has verbalized issues that may exist around source documentation of data collected for credentialing and the security exposure of the vendor community to third party collection of sensitive personal information there has been no data formally presented to the task force that would confirm the claims that have been brought forth during the meetings of the task force. It is in the task force's opinion that the interest of patients are not advanced by the types of credentialing policies that request health care industry representative's unsecure and unprotected personal identification information that may lead to identification fraud or theft.

After a thorough review of current health care industry representative credentialing requirements and in conjunction with the objective of creating realistic, meaningful and comprehensive credentialing requirements, the task force puts forth the following definitions of health care industry representatives for consideration by the Louisiana House of Representatives as categorical definitions for certified health care industry representatives. The definitions and levels of health care industry representatives include the following:

Vendor: Any individual, company, agent, or representative that is involved in the selling, marketing, care, treatment, and/or health care services to a hospital and/or its patients, including but not limited to pharmaceutical companies, device (or DME) manufacturers, nutritional products, equipment, health care service providers, or other medical products or services.

Level 0: No Fee Vendor

Vendors who access the facility but are not required to provide any credentials or documentation. These individuals do not access clinical areas, do not provide technical assistance, do not operate equipment, do not enter patient care areas, and do not provide assistance or consult with patient care staff or clinicians. (Example: Morticians and delivery vendors)

Level 1: Non-Clinical Vendor

Vendors that do not primarily serve in clinical support roles. These Vendors do not provide technical assistance, do not operate equipment, do not generally enter patient care areas, and do not provide assistance or consult with patient care staff. Example: Plant Operations repair vendors, construction labor, maintenance repair contractors)

Level 2A: Clinical Vendor - A

Vendors that primarily serve in clinical support roles. These Vendors may provide technical assistance, may occasionally assist with operation of equipment, and observe or attend procedures with patients. Their role requires them to often work in patient care areas, and/or provide assistance to or consult with patient care staff. They do not have direct involvement in patient procedures. (Example: medical device sales reps, Pharmacy Reps, Representatives calling on the departments of Laboratory, Radiology, Biomed, Diagnostic Reps).

Level 2B: Clinical Vendor - B

Vendors that primarily serve in clinical support roles. These Vendors often provide technical assistance, assist with operation of equipment, calibrate implanted cardiac devices or other implanted pumps or devices, and observe or attend procedures with patients. These Vendor sales representatives are sometimes required to participate in surgical and patient care procedures through direct involvement, such as programming a Cardiac pacemaker, or indirect involvement, such as making recommendations to the surgeon about which appliance to use. Their role requires them to often work in patient care areas, and/or provide assistance to or consult with patient care staff. Example: medical device sales reps, surgical sales rep, technicians)

Level 3: Clinical Contract Vendor

Contract employees/vendors that provide direct patient care and/or services on behalf of an organization. Patient care personnel can include but are not limited to nursing, therapy, pharmacy, dietary, activities staff, drug and alcohol counselors, and nursing assistants/aides. (Example: HealthSouth, Home Health, PIC Line Insertion, Donor Services, and Hospice) (Does not include facility HR Credentialed Agency Personnel)

In addition, the task force puts forth for consideration by the Louisiana House of Representatives the following minimum data set for vendor credentialing firms to follow by source verification of submitted documentation in order for a health care industry representative to become certified vendors in the state of Louisiana:

Recommended Minimum Data Set for Source Verification

	Level 0	Level 1	Level 2A	Level 2B	Level 3
Administrative Credentials					
Employment Verification		X	X	X	X
Proof of Liability Insurance		X	X	X	X
Proof of Criminal Background Check		X	X	X	X
5 Panel Drug Screen		X	X	X	X
Training Credentials					
Blood borne Pathogen Training			X	X	X
OR Protocol Training (Sterile / Aseptic Control)			X	X	X
HIPAA Training		X	X	X	X
Product Training / Competency Verification			X	X	X
Immunization Credentials					
Hepatitis B			X	X	X
Mumps, Measles, Rubella			X	X	X
Tetanus, Diphtheria, Pertussis			X	X	X
Tuberculosis			X	X	X
Varicella			X	X	X
Influenza			X	X	X

VENDOR COMMUNITY PERSPECTIVE

The following recommendations were made by task force members representing the medical vendor community. While they were discussed during the meetings of the task force, representatives from DHH, LHA, and LSU were unable to recommend their inclusion as task force recommendations. While they do not reflect the will of the task force as a whole, they were discussed at length during these meetings and are presented below:

- Although all stakeholders share the common goals of patient safety and quality care, the current environment subjects Health Care Industry Representative's (HCIRs) to widely varying

credentialing requirements, resulting in increased costs and administrative burdens which can also impede access to technology, technical support, and educational resources.

- Some existing HCIR credentialing policies impose standards and credentialing requirements that:
 - (i) are duplicative of existing controls, training and screening processes;
 - (ii) are not reasonably related to the duties performed by HCIRs;
 - (iii) compromise the privacy rights of HCIRs and/or are implemented without assurances that sufficient safeguards, per state and/or federal privacy regulations, are in place;
 - (iv) are inconsistent with existing contractual obligations; and/or
 - (v) are inconsistent with FDA adverse event reporting requirements.
- The efforts of this task force aim to provide the appropriate balance among the goals of patient safety, patient and health care industry representative's privacy. Joint Commission issued a statement that they are not in the business of developing standards of competence for health care industry representatives, nor have they developed standards which dictate source verification or storage.
- To maintain the health care industry representative's privacy; provide less redundancy in annual administrative maintenance documentation, all inpatient and outpatient health care facilities (excluding physician offices and facilities not accredited to accept Medicare/Medicaid patients) will accept Department of Health and Hospitals' Vendor Certification.
- All level 1-3 Health Care Industry Representative's (HCIR's) employers will be required to collect the recommended minimum data set for source verification through Department of Health and Hospitals (DHH). Department of Health and Hospitals through universal data set form available for download and upload via the DHH website. The Task Force discussed that Department of Health and Hospitals (DHH) would charge a nominal fee for this Vendor Certification process.
- Employers will be required to validate and attest to the following:
 1. Health Vaccinations - Health Care Industry Representative's (HCIR's) employer will attest on DHH form: performance of TB test (annually); that the Hepatitis B vaccine was offered per OSHA standard; Mumps, Measles, Rubella (MMR) immunity or documentation of 2 doses of the MMR vaccine and evidence of varicella immunity or 2 doses of the adult varicella vaccine. Privacy concerns dictate that these records should be handled and maintained by the Company and/or HCIR; and
 2. Product and/or General Liability Insurance - Health Care Industry Representative's (HCIR's) employer will attest on DHH form that (HCIR) is covered under employer's General Liability Insurance. Employer will maintain policy coverage - OR - certificate of liability insurance. This includes limits of liability coverage and dates of coverage. No personal liability coverage, liability waiver or personal indemnity should be sought by the hospital/health system; and
 3. Background Verification - Health Care Industry Representative's (HCIR's) employer will attest on DHH form that background verification was performed for each representative upon hire*. Typically this includes: criminal background check; health care sanctions (OIG exclusion, FDA and GSA debarment); Prohibited parties (SDN); sex offender registry; and Drug screen per state regulations* (*various state laws prohibit drug screens in certain instances). Privacy

concerns dictate that these records should be handled and maintained by the Company and/or HCIR; and

4. Training Documentation – Health Care Industry Representative’s (HCIR’s) employer will attest on DHH form that training was successfully completed by the HCIR in the following areas:
 - (1) Device/Procedure-Specific Training;
 - (2) HIPAA / Patient Confidentiality & Privacy training;
 - (3) Conduct Policies and Procedures- - letter from Company verifying training and/or stating that Company requires a HCIR to be trained on policies and procedures consistent with a nationally recognized applicable industry code of ethics such as the AdvaMed Code of Ethics;
 - (4) OSHA/Blood Borne Pathogens; and
5. Upon acceptance of the HCIR form, DHH will issue a credentialing clearance to the HCIR employer. All vendor credentialing certification submitted for Health Care Industry Representatives (HCIR) employed within the state of Louisiana are subject to audit and fines for non-compliance.
6. In addition to the above DHH Vendor Certification, facilities may require Health Care Industry Representatives (HCIR) to complete Hospital Unit Orientation/Policies and Procedures – If appropriate, unit orientation with procedural area should be conducted and documented by the hospital (e.g., if appropriate, OR protocol, Procedure Suite protocol, ED protocol, and/or ICU protocol). If there are hospital rules and policies related to appointments, check-in processes and/or other requirements (e.g., knowledge of emergency procedures), these policies and procedures should be communicated and observed.

CONCLUSION

It is the conclusion of the Medical Vendor Credentialing Task Force that the credentialing of medical vendors who are involved in the selling, marketing, care, treatment, and/or health care services to Louisiana’s inpatient and outpatient health care facilities (excluding physician offices and facilities not accredited to accept Medicare/Medicaid patients would be better served if the Louisiana Legislature were to pass a minimum data set requirement that would ensure that any entity providing credentialing services in Louisiana would have verified a standard minimum set of data. The data required for credentialing should be meaningful and strive toward ensuring the safety of the patient population and driving toward high quality health care.

Although the medical vendor community believes it is in the best interest of the state of Louisiana to mandate a single source for medical vendor credentialing, the task force did not reach agreement on the proposals set forth by the medical vendor community in this report. In selecting one entity to provide these services, Louisiana would be establishing a state-sponsored monopoly that would eliminate the right of hospitals, clinics, ambulatory surgery centers and other facilities to contract for services in the free market. To produce such a monopoly for medical vendor credentialing in Louisiana would only result in higher costs and lower quality by eliminating the ability of the competitive marketplace to drive demand.

At this juncture, the Medical Vendor Credentialing Task Force recommends all the above stated proposals for consideration in response to HR 150 of the 2010 Regular Session.

Regular Session, 2010

HOUSE RESOLUTION NO. 150

BY REPRESENTATIVE SCHRODER

A RESOLUTION

To urge and request the Department of Health and Hospitals to create a Medical Vendor Credentialing Task Force to study the current medical vendor credentialing process, to make recommendations for the establishment of a uniform and reciprocal system of vendor credentialing, and to submit a report containing the results of the study and any recommendations to the member representing House of Representatives' District Number 77 and the House and Senate committees on health and welfare no later than February 1, 2011.

WHEREAS, medical vendors play an important role in the delivery of health care in Louisiana; and

WHEREAS, while the state has an interest in ensuring that our health care facilities remain secure and infection free, the state also has an interest in ensuring that our medical vendors have access to health care facilities so that they may deliver necessary medical supplies; and

WHEREAS, while vendor credentialing is important, the state must balance safety concerns for hospitals with cost and burden to medical vendors, who currently are subjected to multiple expensive background checks, trainings, and health tests, creating an unnecessary burden on vendors; and

WHEREAS, it would be most fair, efficient, consistent, and cost-effective to create a uniform and reciprocal system of vendor credentialing that serves both the needs of the health facilities and the needs of the medical vendors.

THEREFORE, BE IT RESOLVED that the House of Representatives of the Legislature of Louisiana does hereby urge and request the Department of Health and Hospitals to create the Medical Vendor Credentialing Task Force (hereafter referred to as task force) to undertake all necessary study and analysis and to make recommendations for

the establishment of a uniform and reciprocal medical vendor credentialing system. The recommendations may include but are not limited to the following:

(1) Requirements of the vendor to receive uniform and reciprocal credentialing, such as receipt of appropriate health vaccinations, background screenings, proof of liability insurance, and the completion of training in appropriate health care law and hospital protocol.

(2) Suggestions for the amount of fees appropriate to accomplish uniform and reciprocal credentialing.

(3) Recommendations as to which entity would be responsible for the oversight and implementation of a uniform vendor credentialing system.

(4) Any necessary new statutes or rules that must be promulgated in order to create a new medical vendor credentialing system.

BE IT FURTHER RESOLVED that the task force shall be staffed by the Department of Health and Hospitals and shall be composed of seven members appointed by the secretary consisting of representatives from the Department of Health and Hospitals, the Louisiana Hospital Association, the medical vendor industry, and any other persons with an interest in uniform credentialing. In making these appointments, the secretary shall use his best efforts to appoint members who will represent the interested industries equally.

BE IT FURTHER RESOLVED that the task force shall hold its organizational meeting within sixty days after adjournment sine die of the 2010 Regular Session of the Legislature on the call of the secretary of the Department of Health and Hospitals, and that at such organizational meeting, the task force shall elect a chairman and vice chairman by majority vote and shall adopt any necessary rules for its own procedures.

BE IT FURTHER RESOLVED that a report containing the study results and any recommendations shall be submitted to the member representing House of Representatives' District Number 77 and the House and Senate committees on health and welfare no later than February 1, 2011.

SPEAKER OF THE HOUSE OF REPRESENTATIVES