HB 690

Department of Legislative Services

Maryland General Assembly
2011 Session

FISCAL AND POLICY NOTE

House Bill 690 (Delegate Morhaim, *et al.*)
Health and Government Operations

Maryland Cardiovascular Patient Safety Act

This bill requires a cardiovascular catheterization laboratory to hold, by May 31, 2014, either a current accreditation with an accreditation organization or a certification with the Department of Health and Mental Hygiene (DHMH). DHMH may (1) use consultants to meet these requirements; and (2) set and impose reasonable fees upon a laboratory to cover the costs of carrying out these requirements. DHMH must adopt regulations to carry out the bill's provisions.

The bill takes effect June 1, 2011.

Fiscal Summary

State Effect: General fund expenditures increase by $53,400 in FY 2012 to hire one full-time health facility surveyor to assist with development of the required regulations and, beginning in the following year, oversight of the certification process. Revenues are not affected in FY 2012 but increase beginning in FY 2013 due to certification fees collected to offset costs. Future year expenditures reflect annualization; inflation; presumed increases in certification fees; and, beginning in FY 2013, the cost of consulting services associated with the peer review process.

(in dollars)	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
GF Revenue	$0	-	-	-	-
GF Expenditure	$53,400	$329,800	$336,100	$342,500	$349,300
Net Effect	($53,400)	(-)	(-)	(-)	(-)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Bill Summary: "Cardiovascular catheterization laboratory" means a hospital-based laboratory that performs cardiovascular diagnostic or percutaneous coronary intervention (PCI) procedures to diagnose and treat coronary artery disease. An accreditation organization must accredit a cardiovascular catheterization laboratory by inspecting and surveying procedures performed at the laboratory and comparing the results to nationally recognized standards. An accreditation organization must be independent, have an adequate oversight board and site visit personnel, and be approved by DHMH.

A cardiovascular catheterization laboratory that does not hold an accreditation must apply for certification with DHMH. Such certification must consist of periodic review and evaluation of the laboratory's facilities, health care providers and providers' privileges, indications for procedure, procedural conduct, patient outcomes, radiation safety and exposure, reporting of results including validation of reported data, and quality assurance. Review and evaluation for certification must consist of spot audits and site visits. After each review and evaluation, DHMH must issue a report identifying any deficiencies found. Upon receipt of a report of deficiencies, a laboratory must develop a corrective action plan; ongoing surveillance of the laboratory must document action taken to carry out the plan.

DHMH must grant full certification, which is valid for two years, to a laboratory that meets all of the standards established by the department. DHMH may, alternatively, either grant provisional certification or deny certification. A laboratory that is granted provisional certification must make substantive corrections of deficiencies in accordance with a corrective action plan within six months after the provisional certification is granted; otherwise, the laboratory must be denied certification and must resubmit all data at a later time for reconsideration.

Each cardiovascular catheterization laboratory is subject to periodic peer review by one of the following independent entities: a hospital within a hospital system operating in the State; a consortium of hospitals; or an accreditation organization. Peer review must be based on cases either selected at random, for their appropriateness, or involving complications or unexpected outcomes. The peer review process must address a range of elements, as specified by the bill, and the findings from peer review must be compared to previous State experience and appropriate national standards.

DHMH, the Maryland Health Care Commission, and the Health Services Cost Review Commission (HSCRC) must give the same consideration to data from the CathPCI Registry as given to data from other sources to determine appropriate use criteria and quality and performance measures for hospitals and health care providers using cardiovascular or PCI procedures. "CathPCI Registry" means the National Cardiovascular Data Registry that assesses the characteristics, treatments, and outcomes of cardiac disease patients who receive cardiovascular diagnostic or PCI procedures.

Current Law/Background: Recent allegations concerning unnecessary coronary stent procedures performed at St. Joseph's Medical Center in Towson have raised concerns regarding the State's ability to readily identify other instances in which unnecessary procedures are being undertaken. Accordingly, DHMH is in the process of implementing regulatory changes to strengthen and change the focus of hospital peer review standards by requiring the review process to address the volume and medical necessity of procedures performed. DHMH advises that new regulations will require hospitals to implement clear and consistent standards for peer review and that records will be maintained to track and audit the peer review process.

To prevent or detect the occurrence of unnecessary procedures in the future, the department also plans on broadening current regulations related to patient safety. Currently, regulations require only death or serious injury to be reported to the Office of Health Care Quality, and uncertainty exists as to whether an unnecessary procedure causes serious injury. Thus, DHMH is in the process of broadening reporting requirements to require the report of an unnecessary procedure regardless of whether harm in the traditional sense has occurred.

DHMH advises that hospital data available to HSCRC may be used to identify hospitals that overutilize coronary stent procedures; however, on-site clinical investigation is necessary to confirm whether procedures or services are overutilized. DHMH advises that it does not currently have the resources to conduct systematic on-site clinical review of hospital records, although it may be able to conduct periodic "spot checks" to investigate trends revealed in data analysis. HSCRC has begun to review stent procedures by using hospital discharge data and consulting with both the U.S. Department of Health and Human Services and cardiologists with clinical expertise in the utilization of cardiac stents; according to DHMH, such reviews may be extended to nonhospital settings where other costly medical procedures take place.

Additional data on cardiac procedures are collected by the Maryland Health Care Commission, which has organized a standing Maryland State Cardiac Data Advisory Committee to assist in implementing coronary stent procedure data reporting requirements.

The American College of Cardiology (Maryland Chapter) and the Society of Cardiovascular Angiography and Interventions have jointly recommended legislation to require (1) that all cardiovascular catheterization laboratories in the State be accredited by a national accrediting organization and subject to peer review; and (2) the use of the National Cardiovascular Data Registry for quality and appropriateness of care reviews.

State Fiscal Effect: Revenues are not affected in fiscal 2012 because the certification process is not expected to begin until fiscal 2013 and, therefore, no certification fees will be collected until then.

General fund expenditures increase by $53,449 in fiscal 2012 to hire one full-time health facility surveyor to assist with development of the required regulations and, beginning in the following year, oversight of the certification process. The estimate includes a salary, fringe benefits, and ongoing operating expenses.

Health Facility Surveyor	1
Salary and Fringe Benefits	$52,241
Operating Expenses	1,208
Total FY 2012 State Expenditures	**$53,449**

Future year expenditures include a full salary with 4.4% annual increases, 3% employee turnover, and 1% annual increases in ongoing operating expenses.

Future year expenditures also include consulting services associated with the certification process beginning in fiscal 2013. The bill's peer review provisions necessitate that physicians be active in the new certification process. Accordingly, DHMH advises (and Legislative Services concurs) that consultation services are necessary to implement the bill. Based on rates provided by a consultation firm that was active in the review of St. Joseph's Medical Center, DHMH advises that the cost to conduct the required peer review for 25 laboratories is $803,625. This estimate assumes that, in conducting the review, three physicians each spend three days visiting each laboratory. In light of the complexity of the issues involved, Legislative Services generally agrees with this assumption. However, because certification is valid for two years and is not *required* until May 31, 2014, Legislative Services estimates that these costs will be distributed over rolling two-year periods. In addition, because DHMH advises that larger hospitals with such laboratories are likely to seek accreditation rather than certification, Legislative Services assumes that only 16 hospitals with these laboratories will have to be certified by DHMH. Accordingly, general fund expenditures increase by $257,160 in fiscal 2013 to reflect the cost of contractual services associated with reviewing eight laboratories per year. Future year expenditures reflect inflation.

The bill does not specify the fee for certification, but assuming fees are set to offset costs of the review process, each hospital laboratory certified is expected to pay a certification fee of approximately $30,000 to $35,000. Given that certification is valid for two years, revenues are assumed to be distributed evenly over each two-year period. Although the timing of revenues and expenditures may not align perfectly, it is assumed that general fund revenues from certification fees will generally match the expenditures necessary to carry out the bill's requirements.

Additional Comments: Hospital expenditures are likely to increase significantly under the bill. The University of Maryland Medical System advises that it expects to spend at least $95,000 to $120,000 annually to meet the bill's requirements.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene, University of Maryland Medical System, Department of Legislative Services

Fiscal Note History: First Reader - March 1, 2011
ncs/mwc

Analysis by: Jennifer A. Ellick

Direct Inquiries to:
(410) 946-5510
(301) 970-5510