**SB 756**

# Department of Legislative Services

Maryland General Assembly
2014 Session

## FISCAL AND POLICY NOTE

Senate Bill 756 (Senator Muse)
Finance

**Commission on Kidney Disease - End-Stage Renal Disease Quality Incentive Program - Regulations**

This bill requires the State Commission on Kidney Disease to adopt regulations that incorporate the federal Department of Health and Human Services' National Strategy for Quality Improvement in Health Care's End-Stage Renal Disease (ESRD) Quality Incentive Program.

## Fiscal Summary

**State Effect:** General fund expenditures increase by at least $180,400 in FY 2015 to hire three full-time employees to implement the federal ESRD Quality Incentive Program, as discussed below. Future years reflect annualization and inflation. Revenues are not affected.

| (in dollars) | FY 2015 | FY 2016 | FY 2017 | FY 2018 | FY 2019 |
|---|---|---|---|---|---|
| Revenues | $0 | $0 | $0 | $0 | $0 |
| GF Expenditure | 180,400 | 229,100 | 239,600 | 250,600 | 262,100 |
| Net Effect | ($180,400) | ($229,100) | ($239,600) | ($250,600) | ($262,100) |

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

**Local Effect:** None.

**Small Business Effect:** Meaningful.

## Analysis

**Current Law/Background:**

*Licensure of Kidney Dialysis Centers in Maryland*

The Department of Health and Mental Hygiene's (DHMH) Office of Health Care Quality (OHCQ) *licenses* all freestanding kidney dialysis centers under its regulations regarding freestanding ambulatory care facilities. A "kidney dialysis center" means a facility that provides hemodialysis or chronic peritoneal dialysis, but it does not include a center or service owned or operated by a hospital. Under these regulations, a kidney dialysis center must be in compliance with all applicable federal, State, and local laws and regulations and must also submit a Medicare certification as a condition of licensure. The administrator of a kidney dialysis center must ensure that the center has a quality assurance program.

*Maryland Kidney Disease Program, Fund, and Commission*

In Maryland, there is a Kidney Disease Program and Fund (KDF), which was established to assist citizens with the costs of treatment for kidney disease as a payor of last resort. In order to receive funding from KDF, a person must meet medical residency, and other nonmedical eligibility requirements, as established by DHMH. One of these requirements is that a program recipient must apply for eligibility in Medicaid *and* the Medicare Part B or Part D Program, within 60 days of notification to do so by DHMH.

KDF is the payor of last resort, which means the program may provide financial assistance to certified Maryland ESRD patients only after all other federal, State, and private medical insurance coverage has been pursued.

There is also a Maryland Commission on Kidney Disease, which promotes quality health care in the field of nephrology and transplantation by certifying dialysis and transplant centers, receiving and resolving complaints from interested parties, and setting standards for the practice of chronic dialysis and transplantation that reflect new and emergent developments in the practice of chronic dialysis and kidney transplantation. The commission is charged with adopting physical and medical standards for the operation of dialysis and transplant centers. The commission may not adopt any standard that prevents an individual from receiving federal medical or financial aid. DHMH is charged with promulgating regulations that implement quality of care standards adopted by the commission to govern nonmedical eligibility criteria for recipients and reimbursement of providers and recovery of Kidney Disease Program expenditures from recipients and third parties.

The commission *certifies* treatment centers that meet the standards that the commission adopts for providing services to recipients. There are 125 certified treatment facilities in the State. The commission inspects certified facilities annually. Although certification is voluntary, a treatment center must be certified by the commission in order to receive reimbursement from KDF. However, the commission is not in charge of KDF payments, the level of payment, or how payment is disbursed. Similarly, the commission has no jurisdiction over Medicaid or Medicare payments or standards. Treatment centers must also be licensed by OHCQ in order to treat patients, but this licensure is separate from certification. There are 2,101 beneficiaries of the Kidney Disease Program, and 9,000 to 10,000 ESRD patients in the State. Most of these patients are Medicare recipients.

*Federal National Strategy for Quality Improvement in Health Care's End-Stage Renal Disease Quality Incentive Program*

The federal Centers for Medicare and Medicaid Services (CMS) administer the ESRD Quality Incentive Program to promote high-quality services in outpatient dialysis facilities treating patients with ESRD. The program links a portion of payment directly to a facility's performance on quality of care measures. Thus, the program can reduce payments to ESRD facilities that do not meet or exceed certain performance standards by up to 2%. All ESRD facilities in the United States are subject to CMS quality incentive program standards if they receive federal payment from Medicare. The program evaluates whether a facility meets the standards.

CMS conducts regulation and enforcement activities to ensure that Medicare dialysis facilities comply with federal standards for patient health and safety and quality of care. CMS surveys dialysis facilities approximately every 36 months and also conducts investigations of complaints on an "as needed" basis.

According to the CMS quality incentive program website, the standards have changed over time, and three periods apply on a yearly basis: (1) the payment year (PY); (2) the comparison period; and (3) the performance period. The comparison period is the time during which data is gathered on all dialysis facilities to establish the baseline to evaluate a facility's future performance. The performance period follows the comparison period and is used to calculate the ultimate score and to determine whether a facility will have payment reductions. If payment reductions occur, then that reduction applies to payments rendered during the payment year.

According to the Medicare Learning Network, the ESRD Quality Improvement Program was added to the Social Security Act by the Medicare Improvements for Patients and Providers Act of 2008. The purpose of the amendment was to promote patient health by providing a financial incentive for renal dialysis facilities to deliver high-quality patient care.

The National Quality Strategy establishes six domains of quality measurement that are embodied in CMS's ESRD Quality Improvement Program:

- Care Coordination – promoting effective communication and coordination of care.
- Population/Community Health – working with communities to promote wide use of best practices to enable healthy living.
- Safety – making care safer by reducing harm caused in the delivery of care.
- Affordability – making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery methods.
- Patient and Family Engagement – ensuring that each person and family are engaged as partners in their care.
- Treatment and Prevention of Chronic Disease – promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.

To ensure these domains of quality are realized, CMS developed various clinical measures and reporting measures to evaluate and ultimately score facilities. The clinical measures relate to anemia management, adult hemodialysis, adult peritoneal dialysis, pediatric hemodialysis, vascular access type (either arteriovenous fistula or catheter), National Healthcare Safety Network bloodstream infection in hemodialysis outpatients, and hypercalcemia. The three reporting measures are In-Center Hemodialysis Consumer Assessment of Health Care Providers and Systems Patient Satisfaction Survey, mineral metabolism, and anemia management. CMS has a complicated scoring system through which facilities are evaluated on performance, improvement, and benchmark comparisons and given a score. This score is used to determine whether payment to a facility is reduced (by up to 2%).

**State Fiscal Impact:** The bill significantly expands the commission's authority and responsibilities. The commission does not currently calculate payments or collect data on individual patient experiences (unless investigating a complaint), and it is not involved in payment for ESRD treatment. The commission advises that it cannot absorb the bill's requirements with existing staff levels and will need to hire three full-time employees to handle the additional workload. The Department of Legislative Services (DLS) agrees, assuming the bill could be implemented as discussed further below.

Although the commission's activities are special funded and the new responsibilities under the bill would likewise be eligible for special funding, DLS advises that general funds must be used for this purpose. The bill does not modify the funding source for the commission by raising the cap on the fee the commission can charge facilities for certification. Facilities are charged on a pro-rated scale, based on the size of the facility.

Currently, most facilities already pay the maximum $1,500 fee allowed under law. Thus, general funds must be used to cover the additional costs for this bill.

Accordingly, general fund expenditures increase by at least $180,434 in fiscal 2015, which accounts for the bill's October 1, 2014 effective date. This estimate reflects the cost of hiring one full-time fiscal service officer, one full-time nurse facility surveyor, and one full-time data specialist to inspect facilities according to the quality incentive program standards, collect data on the 10,000 dialysis patients in the State, interpret the reimbursement schedule, handle the pay for performance reimbursement adjustments, and develop and maintain a computer system relating to data collection and reimbursement. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

| | |
|---|---|
| Positions | 3 |
| Salaries and Fringe Benefits | $160,799 |
| Operating Expenses | 19,635 |
| **Total FY 2015 State Expenditures** | **$180,434** |

Future year expenditures reflect full salaries with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

However, the bill does not affect Medicare expenditures or revenues because the commission does not have jurisdiction over these funds.

The estimate above assumes that the commission can implement the national ESRD Quality Incentive Program as envisioned by the bill. However, DLS advises that practical concerns make the implementation of the State-level quality incentive program infeasible:

- The commission does not currently have access to patient records. Since several of the quality measures require collection of patient treatment data, it is unclear how the commission will conduct these measures in order to score facilities.

- Maryland does not have any control over the amount of Medicare payments because reimbursement rates are set at the federal level. DHMH may be able to change the reimbursement rate for Medicaid payments, but it is unclear whether it could do so. The commission does not play any role in rate-setting for Medicare, Medicaid, or the Kidney Disease Program.

Moreover, even if able to be implemented, the bill establishes a duplicative requirement for facilities. Specifically, every facility in the State must have Medicare certification in order to receive a license to operate from OHCQ. Additionally, in order to receive

Medicare payment from the federal government, every facility (both in the State and nationwide) is subject to the ESRD Quality Incentive Program, which is enforced by CMS. Thus, the bill establishes parallel State and federal oversight and penalties for facilities that provide treatment to ESRD patients. CMS already has the authority to impose a 2% penalty on payments to kidney disease facilities that do not meet certain standards. If the commission also imposes this same penalty, it means facilities could be subject to a total penalty of 4%.

**Small Business Effect:** Facilities are subject to duplicative requirements and potentially double penalties.

## Additional Information

**Prior Introductions:** None.

**Cross File:** None.

**Information Source(s):** Department of Health and Mental Hygiene, Department of Legislative Services

**Fiscal Note History:** First Reader - March 11, 2014
ncs/ljm

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