New Jersey’s Experience: Mandatory Estimated Glomerular Filtration Rate Reporting

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The passage of legislation in New Jersey mandating the calculation and reporting by clinical laboratories of the estimated glomerular filtration rate whenever a serum creatinine test is performed resulted in a flurry of activity by laboratories to bring their facilities into compliance. After guidance provided by the Department of Health and Senior Services in November 2005 regarding legislative intent, New Jersey’s clinical laboratories, including more than 80 acute care hospital laboratories, successfully implemented estimated glomerular filtration rate reporting by July 2006. This reporting, however, was not achieved without controversy and logistical barriers. Despite these issues, the initial feedback from physicians in response to receiving estimated glomerular filtration rate values on test reports as mandated by state law has been largely favorable. With more than 3.5 million estimated glomerular filtration rate values reported to the department by a sampling of large independent (n = 3), physician office (n = 4), and hospital (n = 11) laboratories, average estimated glomerular filtration rate values were as follows: 79% of physician office and independent laboratory estimated glomerular filtration rate values were $\geq 60$ ml/min per 1.73 m$^2$, and 2% were $< 30$ ml/min per 1.73 m$^2$; by comparison, 66 and 11% of hospital values were $\geq 60$ and $< 30$ ml/min per 1.73 m$^2$, respectively. Additional studies are necessary to determine whether the intent of the legislation to “aid health professionals in the early diagnosis of kidney disease,” thereby resulting in improved treatment outcomes, is achieved.


### Legislative Process

The likelihood of a bill’s becoming law depends on a number of variables, including the influence of the legislative sponsors in the State Senate and Assembly and the level of support or opposition to the proposed legislation from the governor, legislature, interest groups, and the general public. The passage of the Senate and Assembly bills (S2232/A3922) mandating eGFR reporting by clinical laboratories benefited from the influence of its sponsors in both legislative houses. The sponsors included a member of the Senate Health, Human Services and Senior Citizens committee; the chairperson of the Senate Budget and Appropriations Committee, one of the legislature’s most influential positions; two members of the Assembly Health and Human Services Committee, one of whom is a practicing physician; and several additional co-sponsors in both houses. In addition, representatives of the Delaware Valley Chapter of the National Kidney Foundation (NKF) provided verbal testimony in support of S2232/A3922 at both the Senate and Assembly committee meetings at which the bill was approved to release it to the full Senate and Assembly for a vote. No other verbal or written testimony was received by the Senate and House committees. S2232 was passed by the Senate...
by a vote of 38 to 0 on March 14, 2005, and referred to the Assembly committee. Assembly committee members raised concerns about micromanaging laboratories or getting involved in the practice of medicine, as well as the potential lack of patient information needed to calculate the eGFR, and questioned whether the reporting requirement should be proposed through the rule-making process rather than by statute; however, the support of the Assembly physician sponsor and the NKF resulted in the eGFR bill proposal’s being approved and reported out of the committee to the full Assembly. The eGFR bill proposal was passed by the Assembly on June 23, 2005, by a vote of 75 to 0 to 2. S2232 was signed into law on September 26, 2005, nearly 8 mo after its introduction in the State Senate. The bill provided for an effective date of 60 d after enactment (i.e., November 25, 2005).

Unlike the requirements for promulgation of administrative code rules, such as those for the operation of clinical laboratories, the legislative process does not require written notification to affected parties and a 30- to 60-d public comment period. Lobbyists, constituency groups, and the public can identify and monitor proposed bills of interest on the legislature’s Web site. They may choose to testify or present written comments to the Assembly or Senate committees when a bill is heard, and they may petition legislators directly to oppose or support the bill; however, except for high-profile bills, the general public may not be aware of proposed legislation. Subsequent to the passage of New Jersey’s legislation and the department’s notice to clinical laboratories, several laboratory directors expressed their objections to the legislative mandate and the lack of notification and opportunity to comment on the bill proposal.

**Department Review**

The department’s Division of Public Health and Environmental Laboratories was requested to prepare legislative comments on S2232 in early February 2005 for the commissioner’s consideration. In researching the proposed legislation, it was determined that no other state at that time mandated reporting of the eGFR when serum creatinine testing is performed by clinical laboratories. Further research and discussion with several members of the New Jersey Society of Pathologists and several independent laboratory directors and review of the NKF and National Kidney Disease Education Program (NKDEP) Web sites identified a number of concerns and issues that have subsequently been raised by the CAP, the American Society for Clinical Pathology, the American Association for Clinical Chemistry, and the American Medical Association in their statements opposing mandatory eGFR reporting. These concerns included a lack of consensus on use of the eGFR as a reliable index of chronic kidney disease (CKD); patient variables such as age, muscle mass, dehydration, medication, and hospitalization, which can affect the accuracy of calculated eGFR values; lack of agreement on which eGFR equation to use; instrument and laboratory variability in serum creatinine test results and calculated eGFR values; usurping the authority and decision making of medical practitioners to request the eGFR when they deem that it is clinically indicated; associated costs of modifying laboratory information systems to calculate and report the eGFR and the inability of some laboratory information systems, particularly older systems, to calculate the eGFR at all; and the mandate on laboratories to calculate and report the eGFR when people who order tests may not provide all necessary patient data for the eGFR calculation. These issues and concerns would seem to make the department’s decision to support or oppose mandatory eGFR reporting by clinical laboratories an easy one. All of the concerns and issues listed are valid to some extent and were of concern to the department; however, the deciding factors that resulted in the recommendation to the commissioner of the department to support the proposed mandatory reporting of eGFR values by clinical laboratories were as follows:

- Although the NKF does not take a position on mandatory eGFR reporting, the support of the NKF and NKDEP for eGFR reporting by clinical laboratories and the information on their Web sites influenced the recommendation to support the legislation as the most effective means of ensuring universal eGFR reporting.
- The eGFR for adults can be calculated using the abbreviated Modification of Diet in Renal Disease (MDRD) equation using the age, race, and gender of the patient and his or her serum creatinine value. This information is available on laboratory test requisition forms, except for race. The lack of race information is readily addressed by reporting eGFR values for both white and black patients or providing a calculated value that is applicable to white patients and the conversion factor to be used to calculate the eGFR for black patients.
- Many of the concerns cited by opponents of mandatory eGFR reporting had been recognized and were being addressed by the NKF and NKDEP through efforts such as the Laboratory Working Group’s creatinine standardization program. (Note: In February 2007, the National Institute for Standards and Technology released Standard Reference Material 967, which will help manufacturers and clinical laboratories identify and address interlaboratory variability in creatinine measurement. NKDEP and CAP collaborated with the National Institute for Standards and Technology to develop the Standard Reference Material.)
- Two of the state’s largest independent laboratories already provided eGFR on request.
- A laboratory director in Rochester, NY, where laboratories had been reporting eGFR values for 2 yr as part of a voluntary initiative with NKF, reported to the department that the eGFR reporting project had been well received and that concerns expressed in opposition to eGFR reporting are manageable.
- By 2010, it is estimated that 650,000 people in the United States will require treatment for CKD failure (1–3), a 60% increase from the 406,000 who received treatment in 2001 (2,3). (Note: Recent New Jersey data indicate a 17% increase in the number of New Jerseyans who received dialysis from 2001 to 2005.)
• Equations that estimating GFR on the basis of serum creatinine are more accurate and precise than estimates of GFR from the measurement of serum creatinine alone (4).
• Despite its high prevalence (11%) in adults, kidney disease awareness in the US population is low, including among people with kidney disease (3).
• Diabetes and high BP are the leading causes of kidney disease (5). The number of New Jerseyans who are at risk for CKD includes 426,000 adults with diagnosed diabetes as of 2002 and an estimated 26.1%, or 1,700,000, New Jersey adults with high BP in 2001 (6).
• Kidney disease is the eighth leading cause of death in New Jersey (6).
• The department concluded that the potential public health benefits of eGFR reporting by clinical laboratories for the approximately 2 million New Jerseyans who are at risk for CKD outweighed the concerns raised by those who opposed mandatory reporting.

Subsequent to the preparation of comments for the commissioner’s consideration, it is not known whether additional discussions were held between the department, the legislative sponsors, other interested legislators, or the governor’s office before the governor signed the eGFR bill into law. It should be noted that the department’s position on proposed legislation may or may not influence the vote of the legislature or the decision of the governor to sign into law, veto, or conditionally veto a bill that has been passed by the legislature. The department has supported bills that the legislature has failed to approve, and, conversely, it has opposed bills that have become law.

**Implementation**

In November 2005, the department provided written notification to clinical laboratories of the eGFR reporting requirement after communication with the bill sponsors through the department’s legislative liaison to clarify legislative intent regarding the reporting of the eGFR for the pediatric population under 18 yr of age and reporting of eGFR for hospitalized patients. Unlike eGFR legislation in other states, which targeted people who are ≥18 yr of age, New Jersey’s law did not specify that eGFR reporting was limited to adults. In response to concerns raised by the department about obstacles facing clinical laboratories for reporting pediatric eGFR, including the lack of height information on test requisition forms, the primary legislative sponsor agreed to focus eGFR reporting for adults aged ≥18 yr, including the reporting of at least one eGFR value for hospitalized patients, whenever serum creatinine testing is performed.

The department’s notice was shared in advance of its mailing with representatives of the New Jersey Society of Pathologists for their comments. The notice was also provided to the New Jersey Hospital Association, which published a notice about the eGFR requirement in its newsletter. Unfortunately, attempts to reach out to the New Jersey Medical Society to have a notice published in its newsletter or on its Web site were unsuccessful. Although the law specified a 60-d effective date for implementation, the department recognized that this timeframe was not practical in view of the programming changes that would be necessary to most laboratory information systems to support eGFR calculation and reporting.

To monitor laboratory compliance with the eGFR reporting requirement, the department surveyed 119 clinical laboratories that were approved to perform serum creatinine testing in March, May, and December 2006. The repeated surveys sought to identify the following: The effective date of eGFR reporting; whether laboratories were reporting eGFR values >60 as >60 ml/min per 1.73 m², as recommended by NKDEP; problems encountered by laboratories that delayed implementation of eGFR reporting; whether laboratories accessed the department’s, NKF’s, or NKDEP’s Web site for information, as recommended in the department’s November 2005 notification; whether educational material was provided to clients by the laboratory before reporting eGFR values; laboratory feedback (positive or negative) from physicians; and preliminary information on eGFR values reported by laboratories, if available.

The survey findings revealed the following: 53% of laboratories that perform serum creatinine testing were reporting eGFR values by January 2006; an additional 30% were reporting eGFR by April 2006, and the remaining 17% of laboratories had initiated reporting by July 2006, 8 mo after the effective date of the legislation. (Note: The department elected not to enforce the law’s effective date as long as laboratories were actively pursuing resolution of laboratory information system [LIS] and other problems delaying implementation.) To the department’s knowledge, one physician office laboratory (POL) chose to stop performing serum creatinine testing because its LIS could not be modified to calculate and report the eGFR. The department is also aware of at least one small independent laboratory that is reporting eGFR by using one of the online equations and keying in the equation variables, a time-consuming process.

Sixty-four percent of laboratories are reporting eGFR values >60 ml/min as >60 as recommended by NKDEP. It seems that some LIS could not be programmed to convert and report all values >60 ml/min as >60 ml/min and are therefore reporting all eGFR as numerical values. In addition, physicians in some hospitals elected to have actual numerical values reported. Although eGFR are less accurate above 60 ml/min, the department is not aware that this inability of LIS to report eGFR values as >60 ml/min has resulted in inappropriate referrals or caused other problems or concerns. Whereas some hospitals were able to program their LIS to report only initial eGFR values for hospitalized patients or to report eGFR values on a quarterly basis, LIS limitations in many hospitals result in eGFR values being reported for every serum creatinine test. For some patients and their physicians, this results in multiple, daily eGFR of limited value being reported throughout the hospital stay. The overwhelmingly single greatest barrier to implementing eGFR reporting was the need for changes to LIS and related software and programming issues. The cost of implementing eGFR reporting by the nearly 120 laboratories in New Jersey that perform serum creatinine testing is unknown; however, several laboratories have reported expending $3000 or more for external LIS consultants, and the cost for time expended by


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internal laboratory or hospital information technology staff to modify their LIS is not known.

Ninety-three percent of the laboratories reported accessing at least one of the Web sites suggested in the department’s initial notice to laboratories for additional information about eGFR reporting recommendations, and 81% reported providing educational materials to clients before or with initial reports. The majority of laboratories reported that feedback from physicians in response to the reporting of eGFR values was positive for the most part, with laboratories reporting 80, 90, 95, and even 100% positive responses; however, a small number of laboratories that responded to this survey reported significant negative feedback. Negative comments from physicians were more frequently associated with hospital laboratories whose LIS could not be programmed to report eGFR values only for the initial serum creatinine tests, by laboratories that reported not providing any educational materials or references to clients before or with initial test reports that contain eGFR values, and by laboratories whose directors are opposed to mandatory eGFR reporting. Surprising, a number of laboratories reported little or no feedback from physicians.

Table 1 provides aggregated eGFR values reported by different types of clinical laboratories that perform serum creatinine testing as follows: Three large independent, 11 hospital, and four POL. The laboratories whose data are reported in Table 1 do not represent a statistical sampling of New Jersey laboratories. The eGFR values reported here were voluntarily reported by these 18 laboratories either on the department’s compliance surveys or at the request of the department. The reported values shown in Table 1 represent all eGFR values calculated and reported by these laboratories and are likely to contain multiple eGFR for some patients, especially those in hospitals whose LIS does not yet permit reporting of the eGFR for the first serum creatinine only. As a result, the hospital laboratories shown are likely to report eGFR values between 30 and 60 ml and <30 ml at a higher rate than if the data represented unduplicated patient eGFR values. This is particularly evident when comparing the 11% of hospital eGFR values <30 ml versus the 2% of values <30 ml for large independent and POL. The more than five-fold higher rate in hospital eGFR values <30 ml is also influenced by other factors, such as acute illness, pregnancy, age, and medications. The extent to which the disparity in eGFR values <30 ml between hospitals and the other laboratories would be reduced if unduplicated patient information were available and how these percentages compare with eGFR values from other states and regions are not known.

Although the sample size of four POL and the total number of eGFR values reported by these POL is limited, it is interesting to observe that the percentages of eGFR values reported by POL and the large independent laboratories are identical: 79% of eGFR values were >60 ml, 19% of values were between 30 and 60 ml, and 2% of values were <30 ml/min per 1.73 m².

Although the department’s surveys did not seek to identify the number or percentage of eGFR that independent laboratories were unable to calculate and report as a result of missing patient age or gender information, there is limited information to suggest that eGFR cannot be reported for between 3 and 8% of serum creatinine tests. The department intends to incorporate provisions in its rules for the operation of clinical laboratories (N.J.A.C. 8:44) to ensure that laboratories are not held responsible for being unable to report the eGFR as a result of missing age or gender information on the test requisition.

**Conclusions**

New Jersey’s clinical laboratories experienced problems in implementing mandatory eGFR reporting, which included software and programming issues, difficulties with older laboratory information systems, and incomplete patient age and gender information necessary for laboratories to calculate and report the eGFR. These problems are consistent with concerns raised before and after the passage of New Jersey’s legislation mandating eGFR reporting. These issues must be dealt with in implementing eGFR reporting on either a mandatory or a voluntary basis.

It is important to note that problems that are associated with the reporting of eGFR values are surmountable and that the response from physicians has been largely favorable. The Delaware Valley Chapter of the NKF reported that eGFR roundtable discussions with primary care physicians, which have included the participation of the primary sponsor of the bill in the State Assembly, who is a practicing physician, have also been very favorably received. In addition, NKDEP’s Laboratory Working Group has made considerable progress to address concerns about interlaboratory variability. The department suspects that many New Jersey laboratories would not be reporting eGFR values today if it had not been legislatively mandated, even with the efforts of the NKF and the NKDEP to encourage voluntary reporting. Although additional work needs to be done regarding laboratory standardization issues and to address concerns raised by groups that are opposed to mandatory eGFR reporting, the department continues to support full implementation of this legislation and its benefits for

<table>
<thead>
<tr>
<th>Type of Laboratory</th>
<th>Total No. of eGFR Reported</th>
<th>Total No. of eGFR 30 to 60 ml</th>
<th>% of eGFR 30 to 60 ml</th>
<th>Total No. of eGFR &lt;30 ml</th>
<th>% of eGFR &lt;30 ml</th>
<th>% of eGFR &gt;60 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large independent laboratories (n = 3)</td>
<td>3,414,364</td>
<td>639,074</td>
<td>19</td>
<td>89,179</td>
<td>2</td>
<td>79</td>
</tr>
<tr>
<td>Hospitals (n = 11)</td>
<td>166,034</td>
<td>38,425</td>
<td>23</td>
<td>18,059</td>
<td>11</td>
<td>66</td>
</tr>
<tr>
<td>POL (n = 4)</td>
<td>4679</td>
<td>910</td>
<td>19</td>
<td>91</td>
<td>2</td>
<td>79</td>
</tr>
</tbody>
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*aGFR, estimated GFR; POL, physician office laboratories.*
New Jerseyans; however, our experience in working with New Jersey clinical laboratories to ensure compliance leads us to offer the following suggestions to any state that is either considering similar legislation or encouraging voluntary eGFR reporting by clinical laboratories:

- Legislation should provide a grace period of at least 6 to 12 mo to allow laboratories to address LIS, programming, and other issues that delay implementation, despite reasonable efforts by laboratories to comply.
- Legislation should include an educational component directed at laboratories, physicians, and other clinical practitioners who order serum creatinine tests, as well as the general public.
- Laboratories should be expected to work with clients to help ensure that patient information (e.g., age, gender) that is necessary to calculate and report the eGFR is provided, but laboratories should not be held legally accountable for being unable to report the eGFR when a practitioner does not provide the required information. The lack of race information is not an acceptable reason for a laboratory not to calculate and report the eGFR, because eGFR values can be calculated and reported without it. Because race is not collected on test requisition forms, most laboratories are using the abbreviated MDRD equation and reporting two eGFR values, one for if the patient is white and one for if the patient is black. Some are reporting a single eGFR value and indicating that it should be multiplied by the adjustment factor of 1.21 if the patient is black. The department believes that calculating and reporting both values is the preferred method because it relieves the physician of having to perform the calculation if the patient is black.
- Studies should be performed to evaluate the impact of mandatory and voluntary eGFR reporting in identifying patients with reduced kidney function, thereby allowing medical interventions to reduce or stop the progression of CKD. These studies should also examine the number and cost of referrals for additional testing and follow-up on the basis of eGFR values of patients who are determined not to have clinically significant reduced kidney function.
- It is important to recognize that differences in current LIS may result in some laboratories’ being unable to report eGFR values above 60 as >60 ml/min per 1.73 m², as recommended by the NKDEP, or may not allow hospitals to report selectively eGFR values only for initial serum creatinine tests for inpatients. Hopefully, newer versions of LIS software will address these issues as laboratories replace existing LIS.
- Further review of the value of reporting eGFR values for hospital inpatients is needed.
- The more inclusive rule-making process, with its required notice to affected parties and 30- to 60-d public comment period, may be a preferable alternative to legislation. Rules are more easily amended than state statute to reflect changes in science and technology.

- The NKF and the NKDEP should identify a model test report for eGFR for clinical laboratories that succinctly includes critical eGFR information for physicians or other practitioners who order serum creatinine tests for their patients.

The implementation of eGFR reporting by clinical laboratories, whether by legislative mandate or on a voluntary basis, cannot be accomplished without the cooperation of physicians, laboratories, regulators, and others to address and resolve the issues mentioned in a concerted effort to identify and reduce the impact of CKD. New Jersey’s clinical laboratories have done a commendable job of addressing the barriers to eGFR reporting in compliance with the legislative mandate. It is likely, however, that any future efforts to impose similar mandates will be met with increased resistance from both laboratories and physicians and their constituency groups; therefore, it is recommended that consideration be given to soliciting the support of all affected parties before proposing legislative or rule-making action. This approach is also likely to result in greater use of such information by recipients of laboratory test reports.

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Disclosures

None.

References