REPORT OF THE
VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Estimated Glomerular Filtration Rate Reporting Among Clinical Laboratory Providers

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 3

COMMONWEALTH OF VIRGINIA
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Introduction

The General Assembly, through Item 302 FF (2) of the 2006-2008 Appropriations Act, directed the Virginia Department of Medical Assistance Services (DMAS) to request that clinical laboratory providers calculate and report to physicians the estimated glomerular filtration rate (eGFR) when performing serum creatinine (or blood) tests on Medicaid recipients over the age of 18. The serum creatinine test measures the amount of creatinine in a patient's blood. Creatinine is a waste product that is formed by the normal breakdown of muscle cells. The eGFR measures how well an individual's kidneys are filtering wastes from the blood and is generated using a formula that accounts for several factors including a patient's serum creatinine level. The eGFR is used by health care providers to monitor patients who have chronic kidney disease (CKD) and to identify patients who are at risk of developing the disease.

The General Assembly also directed DMAS to report on its efforts to increase eGFR reporting among clinical laboratory providers and on the extent to which these providers are complying with this request to the Governor and Chairmen of the House Appropriations and Senate Finance Committees by January 1, 2007. This report is designed to fulfill that directive. The sections that follow provide background information on kidney disease and the eGFR, DMAS efforts to increase awareness among providers about kidney disease and the eGFR, and the results of a survey of clinical laboratory providers conducted by DMAS to determine the extent to which these providers have been complying with its request.

An Overview of Chronic Kidney Disease and the Estimated Glomerular Filtration Rate

Chronic kidney disease (CKD) occurs when an individual experiences a gradual loss of kidney functions over a period of time (usually several years). CKD is a common and serious medical problem. According to the National Kidney Foundation (NKF), approximately 20 million adult Americans (or one in nine adults) have CKD, and an additional 20 million Americans are at risk of developing the disease. Kidney disease, which is the ninth leading cause of death in the United States, is a "silent killer" because it has no specific symptoms. As a result, most people do not realize that they have CKD until it has progressed to end stage renal disease, which is a life threatening condition that is expensive to treat.[1] The NKF reports that approximately 400,000 people in the United States have end stage renal disease, which costs about $25 billion per year to treat.[2] The NKF also reports that roughly 67,000 people die from

[1] End stage renal disease is the final stage in CKD. When a person develops end stage renal disease, kidney replacement therapy, dialysis, or kidney transplant is needed to sustain life.

[2] Based on a review of paid Medicaid claims, 5,609 Virginia Medicaid recipients were identified as having a principal diagnosis of chronic kidney disease in fiscal year (FY) 2006. DMAS also spent approximately $37.4 million on dialysis services for 7,062 recipients during FY 2006.

kidney disease annually. Individuals with diabetes, hypertension, and/or a family history of kidney disease are at an increased risk of developing the disease. The elderly, African Americans, Latinos, Asians, and Pacific Islanders are also at risk of developing CKD.

In the past, health care providers relied upon the serum creatinine test to identify patients with reduced kidney functions. However, the serum creatinine test can produce misleading results because creatinine concentrations in people can vary due to a variety of factors. Consequently, the serum creatinine test may produce a normal reading for a person who actually has kidney disease. Because of this limitation, the NKF and the National Institutes of Health (NIH) recommend that health care providers use the eGFR instead of the serum creatinine test to monitor or identify patients with kidney disease.

The eGFR basically standardizes the serum creatinine test result by including it in a prediction equation that accounts for a patient's serum creatinine level, age, race, and gender. The specific equation that the NIH recommends that clinical laboratories use to calculate the eGFR is known as the Modification of Diet in Renal Disease (MDRD) Study equation. The MDRD equation was developed during a national kidney disease study that was conducted in the early 1990s. A major conclusion of the study was that the MDRD equation produced the "best overall index of kidney function" in Caucasian and African American adults between the ages of 18 and 70. The MDRD equation is evaluated as follows:

> GFR = 186 x $(sCr)^{-1.154}$ x $Age^{-0.203}$ x (1.212 if African American) x (0.742 if female), where sCr is the patient's serum creatinine level.[3]

Because the equation has not been validated in racial and ethnic subgroups other than Caucasians and African Americans, the NIH recommends that laboratory providers report eGFR values for both African Americans and non-African Americans.[4] (The difference between the two estimates is usually about 20 percent.) Health care providers must determine which of the two values is most appropriate for their patients. Despite this limitation, however, the NIH strongly recommends that clinical laboratories use the MDRD equation to estimate eGFR values when performing serum creatinine tests.

To calculate the eGFR using the MDRD equation, clinical laboratory providers have two options available: 1) automatically calculate the values by programming their laboratory information systems to generate them when

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[3] Normal eGFR values vary between 120 and 130 mL/min/1.73 m^2 depending on the patients' age, sex, and body size. A persistently reduced eGFR value indicates that a patient has CKD and an eGFR value below 15 mL/min/1.73 m^2 indicates that a patient has end stage renal disease.

[4] In addition, the MDRD equation has not been validated in children younger than 18, pregnant women, people over 70, and adults with normal renal functions. However, efforts are underway to validate the MDRD equation in additional populations.

creatinine analyses are performed, or 2) manually calculate the values using the free eGFR calculator that is available on the NIH website at www.nkdep.nih.gov/professionals/gfr_calculators/index.htm. In addition, health care providers can manually calculate eGFR values for their patients by downloading a PDA version of the calculator from the NIH website.

DMAS Efforts to Promote Chronic Kidney Disease and eGFR Awareness Among Providers

To comply with the General Assembly's directive to raise awareness among health care providers about kidney disease and the eGFR, DMAS staff met with interested stakeholder groups and prepared two official Medicaid memorandums. Copies of the memorandums are available in the appendix section of this report.

In December 2005, DMAS staff met with staff from the National Kidney Foundation of the Virginias. This meeting led to the creation of a partnership between DMAS, the National Kidney Foundation of the Virginias, the Nephrology Division of the University of Virginia Health System, the Mid-Atlantic Nephrology Associates, the Virginia Primary Care Association, and Anthem-WellPoint. As part of this collaborative effort, DMAS prepared an official Medicaid memorandum that it sent to a variety of health care providers that participate in the Virginia Medicaid program. The memorandum contained information on the risks of chronic kidney disease, the new classification codes that were developed for diagnosing the five stages of chronic kidney disease, and the use of the eGFR for screening patients for kidney disease.

DMAS staff also met with staff from Abbott (a health care company that manufactures drugs that are used to treat patients with CKD) in January 2006, to discuss the feasibility of requesting that clinical laboratory providers calculate and report eGFR values when performing creatinine tests. As a result of this meeting, a budget amendment was introduced during the 2006 General Assembly session that directed DMAS to request that laboratory providers calculate and report eGFR values when performing creatinine tests on Medicaid recipients over the age of 18. This amendment was subsequently passed by the 2006 General Assembly.

In July 2006, DMAS staff conducted a conference call with staff from DaVita (a health care company providing kidney dialysis services) to discuss the agency's efforts to promote eGFR awareness among Medicaid providers. DaVita staff offered to review an official Medicaid memorandum that the agency had prepared to inform providers about the General Assembly's eGFR request and to provide them with guidance on how to calculate the eGFR. After the review, DMAS mailed the memorandum to all in-state and out-of-state hospital and clinical laboratory providers that participate in the Virginia Medicaid program.

Finally, DMAS staff met with members of the Board of the National Kidney Foundation of the Virginias in September 2006. At this meeting, DMAS staff provided the board members with a status report on the agency's efforts to promote kidney disease and eGFR awareness among health care providers.

Results of the DMAS Survey of Clinical Laboratory Providers

To determine the extent to which laboratory providers were complying with DMAS' request to calculate and report the eGFR, DMAS surveyed 994 in-state and out-of-state hospital and clinical laboratory providers in the fall 2006. Prior to reviewing the results of the survey, readers should note that the General Assembly did not mandate that clinical laboratory providers perform the eGFR calculation. Instead, the General Assembly only *requested* that laboratory providers perform the calculation. As a result, laboratory providers that do not perform the calculation are not out-of-compliance with the Virginia Medicaid program.

Responses were received from 132 providers (Table 1). Nineteen of the providers indicated that the General Assembly's request was not applicable to their operations because they did not perform serum creatinine tests. Of the 113 that did perform serum creatinine tests, 38 (or 34%) indicated that they calculated the eGFR, while 75 (or 66%) reported that they did not perform the calculation. Of the providers that performed the eGFR calculation, 29 (or 76%) indicated that they were already performing the calculation prior to the General Assembly's request, while nine indicated that they began performing the calculation due to the request. Reasons given by providers as to why they did not perform the calculation varied. For example, seven indicated that their current laboratory information systems were incapable of performing the calculation; nine indicated that it cost too much to program their laboratory information systems to calculate the eGFR; and fourteen reported that they did not perform the calculation because it was too difficult to identify Medicaid recipients. Interestingly, 34 of the providers that reported that they did not calculate the eGFR indicated that they were in the process of programming their laboratory information systems to generate the calculation as a result of the General Assembly's request.

Conclusions

DMAS fulfilled the requirements of Item 302 FF (2) of the 2006-2008 Appropriations Act by requesting that clinical laboratory providers calculate and report to physicians the eGFR when performing serum creatinine tests on Medicaid recipients over the age of 18. The extent to which laboratory providers have been complying with this request has been documented through a provider survey. While generalizations from the results of the survey are difficult to make due to the small number of providers that participated, the results nevertheless tend to suggest that some laboratory providers were already calculating the

eGFR prior to receiving notification of agency's request, while others were prompted to begin calculating the eGFR as a result of the request. This finding alone suggests that the request made by DMAS was successful at increasing the number of providers that perform the eGFR calculation.

Table 1

Results of the DMAS Survey of
In-State and Out-of-State Hospital and Clinical Laboratory Providers

Question 1: *Does your organization currently calculate and report eGFR values when performing serum creatinine tests?*

	N	Percent
Yes	38	34%
No	75	66%
TOTAL	113	100%

Question 1a: *If your organization does not calculate and report eGFR values, please indicate why by selecting the most appropriate response below.**

4	No staff available to program laboratory information system
4	Only calculated upon request
7	Current laboratory information system cannot perform calculation
9	Costs of programming laboratory information system are too high
14	Difficulty identifying patients who are Medicaid recipients and/or difficulty identifying the race of the patients
34	Currently programming laboratory information system to calculate eGFR

Question 2: *For organizations answering "yes" to question 1, did your organization routinely calculate and report eGFR values when performing serum creatinine tests prior to receiving notification of the General Assembly's request?*

	N	Percent
Yes	29	76%
No	9	24%
TOTAL	38	100%

Source: DMAS staff analysis of data collected during a survey of hospital and clinical laboratory provides.

Appendix A: Study Mandate

2. Effective July 1, 2006, the Department shall request any clinical laboratory performing a serum creatinine test on a Medicaid recipient over the age of 18 years to calculate and report to the physician the estimated glomerular filtration rate (eGFR) of the patient and shall report it as a percent of kidney function remaining. The Department shall provide a status report to the Governor and the Chairmen of the House Appropriations and Senate Finance Committees by January 1, 2007 on its efforts to increase reporting of the eGFR rate to physicians and, to the extent feasible, that clinical laboratories are complying with the requested reporting.

Department of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, Virginia 23219

www.dmas.virginia.gov

MEDICAID MEMO

TO: All In-State General Hospitals, Long Stay Hospitals, Long Stay Inpatient Mental Hospitals, Medical-Surgical Mental Health Retardation Facilities, Physicians, Nurse Practitioners, Podiatrists, Psychiatric Clinical Nurse Specialists, Ambulatory Surgical Centers, Renal Units, Health Department Clinics, Federally Qualified Health Centers, Rural Health Clinics, Independent Laboratories, Substance Abuse Clinics (FAMIS), Psychiatric Residential Inpatient Facilities, HMO Medallion II, Out-of-State Hospitals, Out-of-State Physicians, Out-of-State Laboratories, and Managed Care Organizations (MCOs) Participating in the Virginia Medical Assistance Program

FROM: Patrick W. Finnerty, Director
Department of Medical Assistance Services (DMAS)

MEMO Special

DATE 12/20/2005

SUBJECT: Monitoring Kidney Functions & the Classification Stages of Chronic Kidney Disease (CKD)

As directed by the 2005 General Assembly, DMAS is pleased to announce a new partnership with the Medical Advisory Board of the National Kidney Foundation of the Virginias (NKF-VAs), the Nephrology Division of the University of Virginia Health System, the Mid-Atlantic Nephrology Associates, the Virginia Primary Care Association (VPCA), and Anthem-WellPoint. The partnership is intended to help raise awareness among providers serving Virginia Medicaid beneficiaries about the health risks of chronic kidney disease (CKD) and to encourage the use of estimated glomerular filtration rate (eGFR) values.

According to the National Institutes of Health, 10 to 20 million Americans have kidney disease, and most are not aware of it. Since 1990, the number of Americans with kidney failure has doubled while the number of people starting dialysis or receiving a kidney transplant has increased by 50 percent. As a result, more than 400,000 Americans are currently being treated for kidney failure at a cost of $25 billion annually. Approximately 7.4 million Americans have less than half the kidney functions of a normal adult, while 11.3 million Americans have persistent protein in their urine, which is an early symptom of kidney disease. Individuals with diabetes, hypertension, and/or a family history of kidney disease are at risk of developing the

disease. The elderly, African Americans, Latinos, Asians, and Pacific Islanders are at a higher risk of developing kidney disease.

Diabetes and hypertension are the two main causes of kidney disease. Both conditions can be effectively treated with appropriate lifestyle changes and medication, thereby delaying or even preventing the onset of the disease. There are no specific symptoms of the early stages of kidney disease. As a result, most patients only become aware of their condition after it has progressed to end stage renal disease, which is life-threatening. Unfortunately, when this occurs, they have already lost about 85 percent of their kidney functions.

To assist physicians and other health care professionals with classifying and monitoring patients who suffer from kidney disease, the National Kidney Foundation (NKF) recently revised the Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines. The KDOQI guidelines classify patients into five disease stages based on their estimated glomerular filtration rate (eGFR) values (see Table 1). The eGFR is a measure of how well the patient's kidneys are filtering wastes from the blood. The eGFR is a more accurate level-of-kidney-function test than the traditional serum creatinine test. Because muscle mass and other person-specific factors (such as tubular secretion, generation, and extra-renal excretion of creatinine) can alter creatinine levels, a "normal" reading on the serum creatinine test may actually be misleading.

Table 1

New Classification Stages of Chronic Kidney Disease (CKD) and Estimated Glomerular Filtration Rate (eGFR) Values

Stage	Description	eGFR (mL/min/1.73 m^2)
CKD Stage 1	Kidney damage with normal or ↑ GFR	≥90
CKD Stage 2	Kidney damage with mild to ↓ GFR	60-89
CKD Stage 3	Moderate ↓ GFR	30-59
CKD Stage 4	Severe ↓ GFR	15-29
CKD Stage 5	Kidney Failure	<15 (or dialysis)

Source: National Kidney Foundation. Retrieved December 2, 2005 from www.kidney.org/professionals/kls/pdf/icd9codes.pdf

The eGFR is estimated using a formula that considers the patient's serum creatinine level, age, race, and gender. Normal GFR varies according to age, sex, and body size. In young adults, it ranges between 120 to 130 mL/min/1.73m^2 and declines with age. A decrease in GFR precedes the onset of kidney failure. Thus, a persistently low GFR is a specific indication of CKD.

Patients with eGFR levels below 60 mL/min/1.73 m^2 may suffer from both kidney disease and cardiovascular disease.

The NKF recommends that individuals be tested annually to determine if they are at risk for kidney disease through the use of urine and blood tests. To determine a patient's level of kidney function, a physician can either request that the medical laboratory calculate the eGFR when performing a serum creatinine test or use the free calculator that is available on the National Institutes of Health website at www.nkdep.nih.gov.

To learn more about chronic kidney disease and the services and programs of the National Kidney Foundation of the Virginias, please call 1-804-288-8342 or visit the website at www.kidneyva.org. The foundation's main office is located at 2601 Willard Road, Suite 103, Richmond, Virginia, 23294. Additional information can also be obtained by calling the National Kidney and Urologic Diseases Information Clearinghouse at 1-800-891-5390 or by visiting the National Kidney Disease Education Program's website at:

www.nkdep.nih.gov/professionals/chronic_kidney_disease.htm

ELIGIBILITY AND CLAIMS STATUS INFORMATION

DMAS offers a web-based Internet option (ARS) to access information regarding Medicaid or FAMIS eligibility, claims status, check status, service limits, prior authorization, and pharmacy prescriber identification. The website address to use to enroll for access to this system is http://virginia.fhsc.com. The MediCall voice response system will provide the same information and can be accessed by calling 1-800-884-9730 or 1-800-772-9996. Both options are available at no cost to the provider.

COPIES OF MANUALS

DMAS publishes electronic and printable copies of its Provider Manuals and Medicaid Memoranda on the DMAS website at www.dmas.virginia.gov. Refer to the Provider Column to find Medicaid and SLH (State and Local Hospitalization Program) Provider Manuals or click on "Medicaid Memos to Providers" to view Medicaid Memoranda. The Internet is the most efficient means to receive and review current provider information. If you do not have access to the Internet or would like a paper copy of a manual, you can order it by contacting Commonwealth-Martin at 1-804-780-0076. A fee will be charged for the printing and mailing of the manuals and manual updates requested.

"HELPLINE"

The "HELPLINE" is available to answer questions Monday through Friday from 8:30 a.m. to 4:30 p.m., except on state holidays. The "HELPLINE" numbers are:

1-804-786-6273	Richmond area and out-of-state long distance
1-800-552-8627	All other areas (in-state, toll-free long distance)

Please remember that the "HELPLINE" is for provider use only. Please have your Medicaid Provider Identification Number available when you call.

PROVIDER E-NEWSLETTER SIGN-UP

DMAS is pleased to inform providers about the creation of a new Provider E-Newsletter. The intent of this electronic newsletter is to inform, communicate, and share important program information with providers. Covered topics will include changes in claims processing, common problems with billing, new programs or changes in existing programs, and other information that may directly affect providers. If you would like to receive the electronic newsletter, please sign up at www.dmas.virginia.gov/pr-provider_newletter.asp.

Please note that the Provider E-Newsletter is not intended to take the place of Medicaid Memos, Medicaid Provider Manuals, or any other official correspondence from DMAS.

Department of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, Virginia 23219

www.dmas.virginia.gov

MEDICAID MEMO

TO: All In-State General Hospitals, Independent Laboratories, Out-of-State Hospitals, Out-of-State Laboratories, and Managed Care Organizations participating in the Virginia Medical Assistance Program

FROM: Patrick W. Finnerty, Director
Department of Medical Assistance Services (DMAS)

MEMO Special

DATE 07/26/2006

SUBJECT: Request to Calculate and Report the Estimated Glomerular Filtration Rate (eGFR) Value for Medicaid Recipients

The purpose of this memorandum is twofold. First, it is intended to inform you that the 2006 General Assembly directed DMAS to request that all clinical laboratories calculate and report estimated Glomerular Filtration Rate (eGFR) values when performing serum creatinine tests on Medicaid recipients who are at least 18 years old. This request is effective as of July 1, 2006. Second, the memorandum is intended to notify you that the General Assembly directed DMAS to report on the extent to which clinical laboratory providers are complying with this request by January 1, 2007. Because eGFR values are not reflected in the laboratory claims data, DMAS will survey laboratory providers during the fall 2006 to collect information for its report to the General Assembly regarding compliance with this request.

CALCULATING AND REPORTING ESTIMATED GLOMERULAR FILTRATION RATE (eGFR) VALUES

Because chronic kidney disease (CKD) has become a major public health problem in the United States, the National Institutes of Health (NIH) has recommended that health care providers use eGFR values to monitor patients with CKD and to screen patients who are at risk of developing the disease. The eGFR is a measure of how well a patient's kidneys are filtering wastes from the blood. It is a more accurate measure of a patient's kidney functions than the traditional serum creatinine test. Because muscle mass and other person-specific factors (such as tubular secretion, generation, and extra-renal excretion of creatinine) can alter creatinine levels, a normal reading on the serum creatinine test can be misleading.

The NIH recommends that clinical laboratories use the Modification of Diet in Renal Disease (MDRD) Study equation to calculate eGFR values. According to the NIH, the MDRD equation

is "the most thoroughly validated equation" currently in use for calculating eGFR values. It was developed based on GFR values measured by iodothalamate clearance in a sample of 1,628 adults and validated in a sample of 1,775 African American adults. The MDRD equation accounts for a patient's serum creatinine level, age, race, and gender. The equation is evaluated as follows:

> GFR = 186 x $(sCr)^{-1.154}$ x $Age^{-0.203}$ x (1.210 if African American) x (0.742 if female), where sCr is the patient's serum creatinine level.

Clinical laboratories should report patients' eGFR values along with their serum creatinine test results to the appropriate health care providers once the analyses are completed.

It should be noted that the NIH recommends that labs report eGFR values for both African Americans and non-African Americans because the MDRD Study equation has not been validated in racial and ethnic subgroups other than Caucasians and African Americans. (The difference between the two estimates is usually about 20 percent). The health care providers must determine which of the two values is most appropriate for their patients. Despite this limitation, the NIH strongly recommends that clinical laboratories use the MDRD equation to estimate eGFR values when performing serum creatinine tests.

To comply with the General Assembly's request, DMAS is recommending that all clinical laboratories program their laboratory information systems to automatically calculate eGFR values using the MDRD Study equation when performing serum creatinine tests on Medicaid recipients. The General Assembly is not requesting that clinical laboratories calculate and report eGFR values on Medicaid recipients who are under the age of 18 because the MDRD Study equation has not been validated in children. Information on calculating eGFR values (as well as a free eGFR calculator) is available on the NIH website at: www.nkdep.nih.gov.

General information on chronic kidney disease can be obtained by calling the National Kidney Foundation of the Virginias at 1-804-288-8342 or by visiting the organization's website at www.kidneyva.org. Additional information on kidney disease can also be obtained by calling the national Kidney and Urologic Disease Information Clearinghouse at 1-800-891-5390 or by visiting the National Kidney Disease Education Program's website at: www.nkdep.nih.gov/professionals/chronic_kidney_disease.htm.

CLINICAL LABORATORIES COMPLIANCE WITH THIS REQUEST

As mentioned previously, the 2006 General Assembly directed DMAS to report on the extent to which clinical laboratory providers are complying with this request by January 1, 2007. As a result, DMAS will send you a packet containing a self-administered mail survey questionnaire and a postage paid return envelope in the fall 2006. The survey will only take a few minutes to complete and will ask you questions about your organization's compliance with this request. Once you have completed the questionnaire, please return it in the postage paid return envelope.

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