

**1/25/12**

**NORTH HELP COALITION DIALYSIS “WHITEPAPER”**

**INTRODUCTION**

Deliverable V. of the North HELP contract for the contract year July 1, 2011 to June 30, 2012 reads as follows:

**Deliverable V: Develop a “white paper” on the relative roles of CMS, IPRO, NYSDOH and NKF in emergency preparedness planning for dialysis centers.**

VA: Research relevant federal (CMS) regulations and NYS regulations regarding the roles of CMS, IPRO and NYSDOH in oversight of dialysis providers and their role(s) in emergency preparedness planning, conduct interviews with representatives of IPRO and NKF regarding their oversight of dialysis providers and their roles in emergency preparedness planning, and draft document describing relevant roles of CMS, IPRO, NKF, and NYSDOH in oversight of dialysis providers and their and [sic] emergency preparedness planning. Include information describing any planning happening at either the federal or NYS level for NYC dialysis centers. Submit draft to DOHMH for comment.

This document is intended to satisfy Deliverable VA, which is due on January 30, 2012.

**CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)**

**Conditions for Coverage**

According to a booklet released by CMS,

You can get Medicare no matter how old you are if your kidneys no longer work, you need regular dialysis or have had a kidney transplant, and you have met the following conditions:

- You have worked the required amount of time under Social Security, the Railroad Retirement Board, or as a government employee.
- You're already getting or are eligible for Social Security or Railroad Retirement benefits.
- You're the spouse or dependent child of a person who meets either of the requirements listed above.<sup>1</sup>

Furthermore, according to CMS, “[t]he Social Security Act . . . mandates the establishment of minimum health and safety . . . standards that must be met by providers . . . participating in the Medicare and Medicaid programs. These standards are found in the 42 Code of Federal Regulations. The Secretary of the Department of Health and Human Services has designated CMS to administer the standards compliance aspects of these programs.”<sup>2</sup> CMS’ Survey and Certification Program certifies End Stage Renal Disease facilities (ESRDs) “in the Medicare Program by validating that the care and services of each facility meet specified safety and quality standards, called ‘Conditions for Coverage.’ The Survey and Certification Program provides initial certification of each dialysis facility and ongoing monitoring to ensure that these facilities continue to meet these basic requirements.”<sup>3</sup> CMS further indicates that “State Survey Agencies,” under agreements between the State and the Secretary of the U.S. Department of Health and Human Services, carry out the Medicare certification process.<sup>4</sup>

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<sup>1</sup> Centers for Medicare & Medicaid Services, “Kidney Dialysis and Kidney Transplant Services,” <http://www.medicare.gov/publications/pubs/pdf/10128.pdf> accessed December 13, 2011

<sup>2</sup> Centers for Medicare & Medicaid Services <http://www.cms.gov/CertificationandCompliance/> accessed November 30, 2011

<sup>3</sup> Centers for Medicare & Medicaid Services [http://www.cms.gov/GuidanceForLawsAndRegulations/05\\_Dialysis.asp](http://www.cms.gov/GuidanceForLawsAndRegulations/05_Dialysis.asp) accessed November 30, 2011

<sup>4</sup> Centers for Medicare & Medicaid Services <https://www.cms.gov/CertificationandCompliance/> accessed November 30, 2011

The CMS Conditions for Coverage, which were revised in 2008, contain several provisions regarding emergency preparedness.<sup>5</sup> For example, they require ESRDs to have emergency plans, and undertake training of patients and staff.<sup>6</sup> CMS released a document for patients in October, 1999 entitled “Preparing for Emergencies: A Guide for People on Dialysis” which was revised most recently in 2002.<sup>7</sup>

### **CMS and Kidney Community Emergency Response (KCER) Coalition**

In a July 26, 2006 press release, CMS announced that “CMS and other Federal Agencies have joined with organizations and healthcare providers in the kidney community to form the Kidney Community Emergency Response Coalition and to develop a nationwide disaster response plan.”<sup>8</sup> CMS stated it had hosted a summit in January, 2006 to review “lessons learned” in recent disasters, and described the activities as of the date of the press release as follows:

The Kidney Community Emergency Response Coalition was formed, at the summit, with the National Kidney Foundation serving as the administrative coordination lead for Coalition Activities. . .

Phase I of the Coalition work has been completed with the development and initial dissemination of tools and resources and a national kidney community response plan to help patients, facilities, emergency responders, and coalition members plan for, and respond to, emergencies and disasters.

CMS will assume the administrative coordination lead as the Coalition moves into Phase II.<sup>9</sup>

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<sup>5</sup> 42 Code of Federal Regulations, Section 494.60

<sup>6</sup> 42 Code of Federal Regulations, Section 494.60

<sup>7</sup> KCER <http://www.kcercoalition.com/pdf/101501.pdf>, accessed December 19, 2011

<sup>8</sup> KCER <http://www.kcercoalition.com/pdf/KidneyCoalitionFinal.pdf> , accessed December 5, 2011

<sup>9</sup> KCER Coalition <http://www.kcercoalition.com/pdf/KidneyCoalitionFinal.pdf>, accessed December 5, 2011

The KCER Coalition website indicates that under contract with CMS, “FMQAI: The Florida ESRD Network serves as the administrative support lead for the Coalition.”<sup>10</sup> According to the KCER website, KCER’s mission is as follows: “Collaboratively develop, disseminate, implement and maintain a coordinated preparedness and response framework for the kidney community in the event of any type of emergency or disaster.”<sup>11</sup> With funding from CMS, KCER recently released a document entitled “Disaster Preparedness: A Guide for Chronic Dialysis Facilities, Second Edition.”<sup>12</sup> The KCER website contains a variety of additional resources for patients, providers, and ESRD networks.<sup>13</sup>

Other than KCER, the North HELP Coalition is not aware of any planning being conducted on the federal level for ESRDs in New York City.

## **NEW YORK STATE DEPARTMENT OF HEALTH (NYSDOH)**

In New York State, NYSDOH is the “State Survey Agency” that undertakes pre-opening surveys and ongoing monitoring of ESRDs to determine whether an ESRD meets the CMS Conditions for Coverage. NYSDOH regulations specific to ESRD facilities incorporate by reference the CMS Conditions for Coverage, and also contain additional requirements.<sup>14</sup>

ESRDs in New York State are “hospitals” for purposes of the New York State Public Health Law and are therefore licensed pursuant to Article 28 of the New York State Public Health

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<sup>10</sup> KCER Coalition, <http://www.kcercoalition.com/about.htm>, accessed December 5, 2011

<sup>11</sup> KCER Coalition <http://www.kcercoalition.com/about.htm>, accessed December 6, 2011

<sup>12</sup> KCER [http://www.kcercoalition.com/pdf/Disaster\\_Preparedness\\_-\\_A\\_Guide\\_for\\_Chronic\\_Dialysis\\_Facilities\\_-\\_Second\\_Edition.pdf](http://www.kcercoalition.com/pdf/Disaster_Preparedness_-_A_Guide_for_Chronic_Dialysis_Facilities_-_Second_Edition.pdf), accessed December 29, 2011

<sup>13</sup> KCER <http://www.kcercoalition.com>, accessed December 29, 2011

<sup>14</sup> 10 New York Code of Rules and Regulations, Part 757

Law.<sup>15</sup> Before an ESRD may operate in New York State it must be “established” which includes a determination of need pursuant to the Certificate of Need process.<sup>16</sup> In addition, ESRDs must comply with the requirements that apply to other Article 28 “hospitals.” Since ESRDs are licensed as “hospitals” under the New York State Public Health Law, the Commissioner of NYSDOH has the power

to conduct periodic inspections of facilities with respect to the fitness and adequacy of the premises, equipment, personnel, rules and by-laws, standards of medical care, hospital service, including health-related service, system of accounts, records, and the adequacy of financial resources and sources of future revenues.<sup>17</sup>

According to Aaron Battle, NYSDOH investigates patient complaints it receives regarding quality of care issues in ESRDs.<sup>18</sup>

The North HELP Coalition is not aware of any emergency preparedness planning being conducted on the New York State level for ESRDs located in New York City.

## **END –STAGE RENAL DISEASE NETWORKS**

### **Background**

The CMS Conditions for Coverage require that every ESRD “cooperate with the ESRD Network designated for its geographic area, in fulfilling the terms of the Network’s current statement of

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<sup>15</sup> New York State Public Health Law Section 2801

<sup>16</sup> New York State Public Health Law, Section 2801-a; 10 New York Code of Rules and Regulations section 670.6

<sup>17</sup> New York State Public Health Law, Section 2803

<sup>18</sup> Interview with Aaron Battle, Patient Services Coordinator, ESRD Network 2, January 12, 2012

work. Each facility must participate in ESRD network activities and pursue network goals.”<sup>19</sup> According to the CMS website, “Under the direction of CMS, the End-Stage Renal Disease (ESRD) Network Program consists of a national network of 18 ESRD Networks, responsible for each U.S. state, territory, and the District of Columbia. ESRD Networks service geographic areas based on the number and concentration of ESRD beneficiaries.”<sup>20</sup> The attached CMS document entitled “Summary of the ESRD Network Program” provides further details regarding the ESRD program, including the ESRD Networks’ statutory responsibilities. Those responsibilities include “conducting on-site reviews of facilities and providers, as necessary...”<sup>21</sup>

### **End-Stage Renal Disease Network of New York**

The End-Stage Renal Disease (ESRD) Network of New York’s (Network 2) contract has been awarded to IPRO, an independent, not-for-profit corporation, and the Medicare Quality Improvement Organization (QIO) for New York State.<sup>22</sup>

According to a letter from the ESRD Network of New York, with regard to emergency preparedness, CMS requires all ESRD Networks to:

- Track and publish the open or closed status of dialysis facilities in affected areas.
- Assist in identifying dialysis facilities that can provide services.
- Assist family members and treating facilities in determining the dialysis location of displaced patients in order to exchange critical medical information.
- Coordinate with providers and emergency workers to ensure patient access to dialysis.<sup>23</sup>

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<sup>19</sup> 42 CFR Section 494.180(i)

<sup>20</sup> Centers for Medicare & Medicaid Services <https://www.cms.gov/ESRDNetworkOrganizations/>, accessed December 7, 2011

<sup>21</sup> Centers for Medicare & Medicaid Services <https://www.cms.gov/ESRDNetworkOrganizations/Downloads/ESRDNetworkProgramBackgroundpublic.pdf>

<sup>22</sup> IPRO, <http://www.ipro.org/index/esrdny>, accessed December 6, 2011

<sup>23</sup> Letter from Aaron Battle, Patient Services Coordinator, IPRO, October 21, 2009

The letter indicates that ESRDs were required to complete a “Critical Asset Survey” in order to provide ESRD Network 2 with information in the event of an emergency.<sup>24</sup> According to Aaron Battle, the survey is undertaken annually and the information from the survey standardizes important facility resource information (such as communications, equipment and staff) into a single repository available to the Network in the event of an emergency.<sup>25</sup> Based upon a request from the New York City Department of Health, ESRD Network 2 provided North HELP with the data from the Critical Asset Survey as of July, 2010 for the project.

IPRO has a portion of its website devoted to emergency preparedness and response. It contains links to other websites (such as the KCER website and the New York City Office of Emergency Management website) and links to publications including those of the National Kidney Foundation (NKF) and governmental agencies.

According to Aaron Battle of ESRD Network 2, ESRD Network 2 works closely with NYSDOH (the “State Survey Agency”) to ensure that ESRDs follow the CMS regulations.<sup>26</sup> He indicated that when NYSDOH surveys facilities, surveyors do review compliance with the Conditions for Coverage that relate to emergency preparedness.<sup>27</sup> In addition, he stated that during Hurricane Irene, ESRD Network 2 was in contact with the New York City Office of Emergency Management (OEM) and distributed information from OEM, as it usually does during emergencies.<sup>28</sup> ESRD Network 2 also meets with representatives from offices of emergency

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<sup>24</sup> Letter from Aaron Battle, Patient Services Coordinator, IPRO, October 21, 2009

<sup>25</sup> Interview with Aaron Battle, Patient Services Coordinator, ESRD Network 2, January 12, 2012

<sup>26</sup> Interview with Aaron Battle, Patient Services Coordinator, ESRD Network 2, September 7, 2011

<sup>27</sup> Interview with Aaron Battle, Patient Services Coordinator, ESRD Network 2, September 7, 2011

<sup>28</sup> Interview with Aaron Battle, Patient Services Coordinator, ESRD Network 2, September 7, 2011

management, ESRDs, and ESRD patients throughout New York State as part of a coalition that focuses on emergency preparedness.<sup>29</sup>

## **NATIONAL KIDNEY FOUNDATION (NKF)**

According to the NKF website, the NKF “a major voluntary nonprofit health organization, is dedicated to preventing kidney and urinary tract diseases, improving the health and well-being of individuals and families affected by kidney disease and increasing the availability of all organs for transplantation.”<sup>30</sup> NKF activities include engaging in advocacy, assisting in public health agency, and publishing clinical guidelines under its “KDOQI brand.”<sup>31</sup> The NKF does not engage in any oversight activities of ESRDs. According to Ellen Yoshiuchi of the NKF, the NKF has engaged in emergency preparedness activities such as a national conference call before Hurricane Irene.<sup>32</sup> The NKF’s website includes an “Emergency Preparedness and Response Section” which includes patient education materials.<sup>33</sup>

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<sup>29</sup> Interview with Aaron Battle, Patient Services Coordinator, ESRD Network 2, January 12, 2012

<sup>30</sup> National Kidney Foundation <http://www.kidney.org/about/>, accessed December 6, 2011

<sup>31</sup> National Kidney Foundation <http://www.kidney.org/about/>,  
<http://www.kidney.org/professionals/kdoqi/guidelines.cfm> accessed December 6, 2011

<sup>32</sup> Interview of Ellen Yoshiuchi, Division Program Director, National Kidney Foundation, September 1, 2011

<sup>33</sup> National Kidney Foundation <http://www.kidney.org/help/index.cfm> accessed December 6, 2011