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Constantino, Mike

SEP 22 2011

From: Moon, Shawn K [skmoon@uhlaw.com]
Sent: Wednesday, September 21, 2011 7:02 PM
To: Constantino, Mike
Subject: Letter re In-Center Hemodialysis Station Need Determination
Attachments: Letter re In-Center Hemodialysis Station Need Determination.pdf

**HEALTH FACILITIES &
SERVICES REVIEW BOARD**

Good Afternoon Mike,
Please find the attached PDF copy of a letter written to explain demographic factors of HSAs 7 and 9 which may affect the In-Center Hemodialysis Station Need Determination. This letter is submitted in connection with the U.S. Renal Care Bolingbrook Dialysis, U.S. Renal Care Oak Brook Dialysis, and U.S. Renal Care Streamwood Dialysis certificate of need applications, project numbers 11-025, 11-024 and 11-026, respectively.

Please feel free to contact me with any questions or comments.

Thanks,
Shawn

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September 21, 2011

Mr. Dale Galassie
Illinois Health Facilities & Services Review Board
525 W. Jefferson St., 2nd Floor
Springfield, IL 62761

Re: In-Center Hemodialysis Station Need Determination

Dear Mr. Galassie:

This letter is written to highlight characteristics of the end stage renal disease ("ESRD") population which may affect the accuracy of the Need Determination for the In-Center Hemodialysis Category of Service found in 77 Ill. Admin. Code §1100.630. This letter will briefly examine the statutory requirement for the development of the criteria, standards and rules used to evaluate applications, describe demographic characteristics as they relate to ESRD, provide the demographic changes in the populations of HSAs 7 and 9, and explain how such demographic characteristics affect the Need Determination.

I. Statutory Requirements

As you certainly know, the purpose of the Illinois Health Facilities Planning Act (the "Act") is to "establish a procedure (1) which requires a person establishing, constructing or modifying a health care facility, as herein defined, to have the qualifications, background, character and financial resources to adequately provide a proper service for the community; (2) that promotes, through the process of comprehensive health planning, the orderly and economic development of health care facilities in the State of Illinois that avoids unnecessary duplication of such facilities; (3) that promotes planning for and development of health care facilities needed for comprehensive health care especially in areas where the health planning process has identified unmet needs; and (4) that carries out these purposes in coordination with the Center for Comprehensive Health Planning and the Comprehensive Health Plan developed by that Center."¹ To carry out this purpose, the Act creates the Illinois Health

¹ 20 ILCS §3960/2.

Facilities Services and Review Board (the "Board") and requires the Board to prescribe certain rules, regulations, standards, criteria, procedures or reviews to carry out the provisions and purposes of the Act.² Furthermore, the Act requires the Board to review, revise, and update the criteria, standards, and rules used to evaluate applications for permit **every two years**. "[C]riteria, standards, and rules shall be based on objective criteria."³ This review of the criteria, standards, and rules must include consideration of "[w]hether the criteria and standards take into account issues related to population growth and changing demographics in a community."⁴ As a result, the Need Determination by which an application for permit is reviewed should account for the changing demographics of the community and the related need for health care resources.

II. Observed ESRD Prevalence Rates in Certain Populations

ESRD differentially affects certain populations at rates higher than other populations. For example, ESRD prevalence rates are considerably higher among African-American and Hispanic demographic segments than among non-Hispanic white demographic segments. The African-American ESRD rate has been reported to be 3.6 times that among whites in the United States.⁵ Similarly, peer reviewed academic articles demonstrate that ESRD prevalence among the Hispanic population is materially higher than that of non-Hispanics.⁶ The clinical literature has noted:

a particularly rapid concomitant increase in the incidence and prevalence of end-stage renal disease (ESRD) in Hispanics observed in the United States during the last 2 decades. Compared with non-Hispanic whites, the incidence of ESRD in Hispanics is nearly 2-fold higher. Because of the high frequency of risk factors for ESRD in US Hispanics (eg, diabetes mellitus), it is anticipated that the Hispanic ESRD population will continue to undergo substantial growth.

² 20 ILCS §§3960/4, 12(1).

³ 20 ILCS §3960/12.3.

⁴ *Id.*

⁵ U.S. Renal Data Service, 2010 Annual Data Report: Volume 2 Atlas of End Stage Renal Disease, at 255.

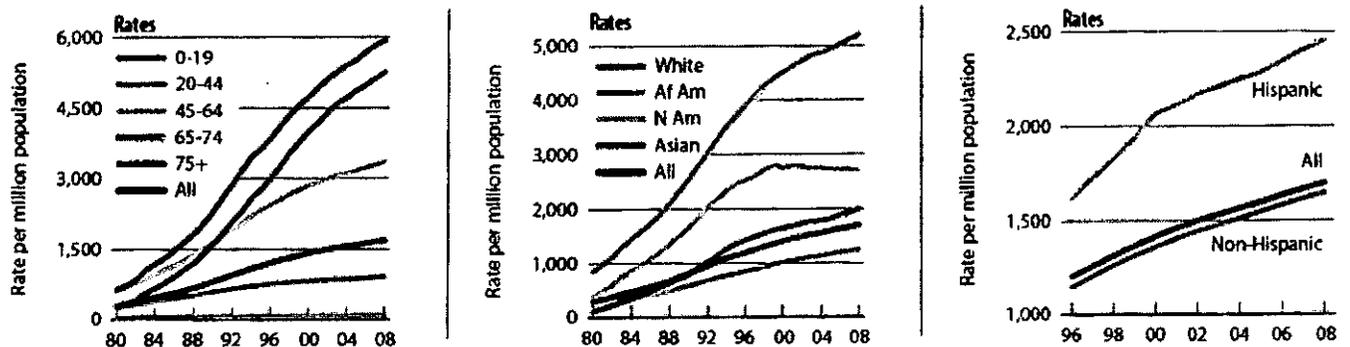
⁶ U.S. Renal Data Service, 2010 Annual Data Report: Volume 2 Atlas of End Stage Renal Disease, at 255; Claudia M. Lora et al., Chronic Kidney Disease in United States Hispanics: A Growing Public Health Problem, 19 *Ethnicity & Disease* 466, at 466 (2009); Michael J. Fischer et al., CKD in Hispanics: Baseline Characteristics From the CRIC (Chronic Renal Insufficiency Cohort) and Hispanic-CRIC Studies, 58(2) *Am. J. Kidney Dis.* 214, at 214 (2011).

Michael J. Fischer et al., CKD in Hispanics: Baseline Characteristics From the CRIC (Chronic Renal Insufficiency Cohort) and Hispanic-CRIC Studies, 58(2) Am. J. Kidney Dis. 214, at 214 (2011).

Obviously, if the 2-fold factor for incidence in this study is accurate, it simply compounds the Need Determination error in not taking into account any increased prevalence for Hispanics when the Hispanic population percentage grows. As a result, communities that demonstrate a growth in both the absolute number and percentage make-up of populations at higher risk for ESRD will experience a greater need for ESRD services.

In addition to ethnic prevalence rates, aging populations have also been associated with higher prevalence of ESRD. As described in the attached Table 1, in 2008, populations aged 65 years and over experienced ESRD prevalence rates that were greater than 3.0 times the overall population.⁷ Specifically, the ESRD prevalence rate for populations aged 65 to 74 years was 5,940.9 per million population as compared to an overall ESRD prevalence rate of 1,698.6 per million population. Similarly, the ESRD prevalence rate for populations aged 75 years and greater was 5,266.4 per million population.

As demonstrated in the following graphs excerpted from the 2010 Annual Data Report, the rates of ESRD prevalence for the populations discussed above far exceed the overall ESRD prevalence rates of other populations.



(Source: U.S. Renal Data Service, 2010 Annual Data Report: Volume 2 Atlas of End Stage Renal Disease, at 258)

These differential rates of ESRD prevalence related to both ethnicity and age result in greater need for ESRD services when populations are composed of greater numbers of individuals who experience higher rates of ESRD prevalence, as has been demonstrated in HSAs 7 and 9.

⁷ See U.S. Renal Data Service, 2010 Annual Data Report: Volume 2 Atlas of End Stage Renal Disease, at 258.

III. Demographic Profile of HSAs 7 and 9

The change in the demographic profiles of the relevant HSAs requires additional stations to ensure that dialysis services are available to area residents. The Need Determination does not sufficiently take into account the demographic mix of the HSA populations and may understate the need for ESRD stations in the relevant HSAs.

A. Ethnic Profile

The changing ethnic profiles of HSAs 7 and 9 increase the need for ESRD services in these areas. As described above, the prevalence of ESRD differs between various ethnic groups which will affect a population's overall ESRD rate as the ethnic mix of the population changes. The communities comprising HSAs 7 and 9 have undergone significant changes in the ethnic mix between the years 2000 and 2010. As demonstrated in the attached Table 2, HSA 7 has seen a dramatic increase in both the "Hispanic or Latino" and "Black or African American alone" populations as tabulated using Census 2000 and 2010 data. Between 2000 and 2010, the "Hispanic or Latino" and "Black or African American alone" populations grew by over 187,000 individuals and 70,000 individuals, or by 47.0% and 20.3%, respectively. HSA 9 has experienced greater diversification through a more profound change in these populations between 2000 and 2010. In fact, the "Hispanic or Latino" population of HSA 9 has grown by 153% from 54,365 individuals in 2000 to 137,978 individuals in 2010. Similarly, the "Black or African American alone" population has grown by 44%, or 30,757 individuals, between 2000 and 2010. As a result of this explosive diversification of HSAs 7 and 9, the ethnic profiles of these HSAs have changed dramatically. In particular, the "Hispanic and Latino" segment of the total population has been significant, expanding from 11.8% to 17.2% in HSA 7 and from 7.8% to 14.4% in HSA 9. As the populations above suffer from a higher prevalence of ESRD, the increase in such populations and resulting changing ethnic profiles of HSAs 7 and 9 increase the need for ESRD services in these areas.

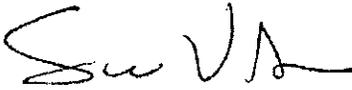
B. Age Profile

The changing demographic profiles of HSAs 7 and 9 with respect to age also increase the need for ESRD services in these areas. As discussed above, populations of individuals 65 years of age and over experience prevalence of ESRD at a greater rate than those under 65 years of age. In HSAs 7 and 9, these populations have grown between 2000 and 2010 and now comprise a greater proportion of the overall population, as demonstrated in the attached Table 3. In HSA 7, the population 65 years of age and over has grown by 28,539 individuals, representing a growth of 6.8%. In HSA 9, this population has experienced explosive growth since 2000. In 2010, the population between the ages of 65 and 74 has grown nearly 53% and the population aged 75 years and over grew nearly 32%. The combined growth of these populations is 42.7% from 2000 to 2010. The growth in these populations represents a significant aging of these communities and will result in greater need for ESRD services.

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We recognize that the Act has been changed multiple times in the past decade. Further, we understand that the General Assembly has transferred significant money from the Illinois Health Facilities Planning Fund to the General Revenue Fund. It should be noted that the State Agency and Board have the responsibility for establishing criteria, standards, and rules for many services in health care, not just dialysis. Consequently, we submit this letter in a constructive spirit to help the State Agency and the Board evaluate these applications in the context of the latest scientific and demographic data.

Sincerely,

A handwritten signature in black ink, appearing to read "Sam Vinson". The signature is stylized and cursive.

Sam Vinson

Table 1.

Figure 2.12*

Prevalent counts & adjusted rates of ESRD, by age

	Number of Patients (in thousands)					Rate per Million Population					
	0-19	20-44	45-64	65-74	75+	0-19	20-44	45-64	65-74	75+	All
1980	2,368	20,212	23,683	9,205	2,790	29.6	263.0	585.1	642.0	273.3	289.6
1981	2,576	23,162	27,278	10,459	3,458	33.1	292.3	678.2	730.5	333.1	330.1
1982	2,855	26,430	30,748	12,148	4,215	37.7	323.9	768.5	840.1	409.7	372.6
1983	3,056	30,199	35,067	15,048	5,791	41.2	361.8	879.2	1,041.0	560.5	430.5
1984	3,240	33,681	38,921	17,126	6,988	44.3	393.4	976.6	1,182.6	662.7	477.6
1985	3,475	37,113	42,430	19,221	8,292	47.8	422.7	1,066.9	1,312.4	782.1	521.9
1986	3,687	40,902	45,772	21,858	9,852	50.9	455.0	1,149.0	1,477.5	910.2	568.7
1987	3,935	44,203	50,233	24,744	11,654	54.4	481.6	1,254.6	1,655.0	1,056.9	619.9
1988	4,133	48,055	55,274	27,634	13,437	57.2	514.4	1,372.4	1,831.6	1,202.9	675.7
1989	4,323	52,458	61,047	31,357	15,819	60.0	550.6	1,507.6	2,053.6	1,395.9	741.6
1990	4,485	57,142	67,095	35,577	18,310	62.3	585.1	1,643.0	2,311.4	1,603.5	808.1
1991	4,637	61,570	74,492	40,641	21,486	64.3	618.7	1,789.6	2,612.6	1,852.1	882.1
1992	4,798	65,704	82,418	45,629	24,817	65.8	652.9	1,934.9	2,898.2	2,108.7	954.1
1993	5,008	69,602	90,442	50,140	27,772	67.4	683.2	2,072.6	3,173.6	2,317.3	1,020.9
1994	5,236	73,091	99,508	55,056	31,616	69.0	709.3	2,220.5	3,464.8	2,585.4	1,092.8
1995	5,467	76,188	107,546	57,920	34,793	70.6	731.8	2,337.8	3,638.3	2,770.4	1,145.2
1996	5,669	79,038	116,459	61,558	38,710	71.8	752.0	2,454.4	3,859.1	3,002.9	1,202.0
1997	5,801	81,514	125,780	65,747	43,298	72.3	769.4	2,559.4	4,122.9	3,262.2	1,259.4
1998	5,955	84,090	136,391	69,462	47,886	73.1	788.9	2,675.0	4,358.2	3,550.9	1,319.1
1999	6,151	86,207	146,438	72,752	52,154	74.7	804.5	2,765.9	4,561.3	3,786.4	1,369.6
2000	6,287	87,827	156,691	76,241	56,778	75.9	816.7	2,857.5	4,745.0	4,017.6	1,418.4
2001	6,416	89,085	166,738	79,848	60,698	77.2	827.2	2,938.8	4,950.6	4,200.0	1,461.9
2002	6,572	89,831	176,637	82,909	65,089	78.9	835.7	3,003.9	5,123.0	4,416.2	1,500.1
2003	6,699	90,507	186,455	85,982	68,773	80.1	843.9	3,062.6	5,270.5	4,592.8	1,533.5
2004	6,868	91,339	196,428	89,338	72,168	81.7	853.6	3,115.2	5,414.3	4,720.0	1,565.7
2005	6,995	92,464	207,054	92,509	75,722	82.8	866.7	3,175.2	5,520.6	4,869.1	1,598.7
2006	7,089	93,906	218,191	97,513	78,706	83.5	882.4	3,236.5	5,701.5	4,992.3	1,635.9
2007	7,205	95,003	228,592	102,788	81,702	84.6	895.4	3,292.5	5,837.4	5,127.8	1,667.8
2008	7,216	95,870	239,158	108,212	84,710	85.0	906.8	3,357.4	5,940.9	5,266.4	1,698.6

(Source: U.S. Renal Data Service, 2010 Annual Data Report: Volume 2 Atlas of End Stage Renal Disease, Figure 2.12)

*Note: The file containing this figure 2.12 is available at www.usrds.org/2010/ese/v2_02.zip

Table 2.

HSA 7 Population by Race (2000 Census Data)

	Cook County	City of Chicago	Suburban Cook County*	DuPage County	Total Population
Hispanic or Latino	1,071,740	753,644	318,096	81,366	399,462
Black or African American alone	1,405,361	1,065,009	340,352	27,600	367,952
Total Population	5,376,741	2,896,014	2,480,727	904,161	3,384,888

HSA 7 Population by Race (2010 Census Data)

	Cook County	City of Chicago	Suburban Cook County*	DuPage County	Total Population
Hispanic or Latino	1,244,762	778,862	465,900	121,506	587,406
Black or African American alone	1,287,767	887,608	400,159	42,346	442,505
Total Population	5,194,675	2,695,598	2,499,077	916,924	3,416,001

HSA 7 Population by Race (2000-2010 Change)

	2000 Total Population	% Total	2010 Total Population	% Total	% Change
Hispanic or Latino	399,462	11.8%	587,406	17.2%	5.4%
Black or African American alone	367,952	10.9%	442,505	13.0%	2.1%
Total Population	3,384,888		3,416,001		

*Cook County excluding City of Chicago

HSA 9 Population by Race (2000 Census Data)

	Grundy County	Kankakee County	Kendall County	Will County	Total Population
Hispanic or Latino	1,552	4,959	4,086	43,768	54,365
Black or African American alone	71	16,065	718	52,509	69,363
Total Population	37,535	103,833	54,544	502,266	698,178

HSA 9 Population by Race (2010 Census Data)

	Grundy County	Kankakee County	Kendall County	Will County	Total Population
Hispanic or Latino	4,096	10,167	17,898	105,817	137,978
Black or African American alone	605	17,187	6,585	75,743	100,120
Total Population	50,063	113,449	114,736	677,560	955,808

HSA 9 Population by Race (2000-2010 Change)

	2000 Total Population	% Total	2010 Total Population	% Total	% Change
Hispanic or Latino	54,365	7.8%	137,978	14.4%	6.6%
Black or African American alone	69,363	9.9%	100,120	10.5%	0.5%
Total Population	698,178		955,808		

Table 3.

HSA 7 Population by Age Group (2000 Census Data)

Age Group	Cook County	City of Chicago	Suburban Cook County*	DuPage County	Total Population	% Total
64 and under	4,746,476	2,597,211	2,149,265	815,367	2,964,632	87.6%
Between 65 and 74	328,628	159,915	168,713	45,558	214,271	6.3%
75 and over	301,637	138,888	162,749	43,236	205,985	6.1%
Total Population	5,376,741	2,896,014	2,480,727	904,161	3,384,888	100.0%

HSA 7 Population by Age Group (2010 Census Data)

Age Group	Cook County	City of Chicago	Suburban Cook County*	DuPage County	Total Population	% Total
64 and under	4,574,346	2,417,666	2,156,680	810,526	2,967,206	86.9%
Between 65 and 74	324,521	151,095	173,426	57,640	231,066	6.8%
75 and over	295,808	126,837	168,971	48,758	217,729	6.4%
Total Population	5,194,675	2,695,598	2,499,077	916,924	3,416,001	100.0%

*Cook County excluding City of Chicago

HSA 9 Population by Age Group (2000 Census Data)

Age Group	Grundy County	Kankakee County	Kendall County	Will County	Total Population	% Total
64 and under	32,928	90,249	49,909	460,656	633,742	90.8%
Between 65 and 74	2,292	6,996	2,474	22,690	34,452	4.9%
75 and over	2,315	6,588	2,161	18,920	29,984	4.3%
Total Population	37,535	103,833	54,544	502,266	698,178	100.0%

HSA 9 Population by Age Group (2010 Census Data)

Age Group	Grundy County	Kankakee County	Kendall County	Will County	Total Population	% Total
64 and under	44,517	98,212	106,354	614,746	863,829	90.4%
Between 65 and 74	3,117	7,952	5,115	36,418	52,602	5.5%
75 and over	2,429	7,285	3,267	26,396	39,377	4.1%
Total Population	50,063	113,449	114,736	677,560	955,808	100.0%