FRESENIUS KIDNEY CARE

Certificate of Need
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April 24, 2018

Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need
NC Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Re: Public Comments, 2019 NC State Medical Facilities Plan, Chapter 14

Dear Ms. Frisone:

I am writing on behalf of Fresenius Medical Care and our related dialysis facilities operating across North Carolina. As you will know, Fresenius Medical Care, and our affiliated facilities, currently operate 112 North Carolina dialysis facilities. In addition, we also have another 20 new facilities which are either CON approved and under development, or, are still under CON review. At the end of 2017, Fresenius related facilities were providing dialysis care and treatment to more than 9,700 North Carolina residents, and another 129 dialysis patients residing out of state. Greater than 50% of the nearly 18,000 dialysis patients receiving care at a dialysis facility in North Carolina are dialyzing in a Fresenius related facility.

Our entire organization is appreciative of your efforts to blend the Semiannual Dialysis Report into the annual publication of the State Medical Facilities Plan. The SDR has been the foundation of ESRD CON applications for greater than two decades. We also realize that merging dialysis reporting into the SMFP is a huge paradigm shift for Fresenius, and all dialysis providers operating in North Carolina.

We offer the following comments regarding potential changes to reporting dialysis station need, statistical reporting, and effort to incorporate dialysis reporting within the SMFP.

1. From the outset we believe that the SMFP can be the appropriate vehicle for reporting dialysis utilization statistics, facility and county station inventories, and need determinations. We strongly encourage the incorporation of the current SDR reporting format which includes:

   Table A, the Patient Origin Report;
   Table B, the Inventory of Dialysis Stations and Calculation of Utilization Rates;
   Table C, the Census of Home Dialysis Patients[1];
   Table D, the ESRD Dialysis Station Need Determinations by Planning Area;
   Table E, the Dialysis Station Need Determination by County.

[1] We are proposing changes to this table; see paragraph 3.

The above reporting formats have generally worked well and provide invaluable information for the citizens of North Carolina, dialysis providers, and appropriate regulatory agencies.

2. Fresenius and related facilities suggest the County Need Determinations should be published within the SMFP. This will result in a single Need Determination schedule each year, as opposed to the SDR process which potentially included County Need Determinations in each publication. However, the reality has been that on average, there has been only one Need Determination each year for the past many years. Publishing the County Need Determinations in the SMFP will have no adverse effect on access to care.

   We recommend that the County Need Determination reviews commence on the following dates:

HSA I, II, III	Review to commence on May 1
HSA IV, V, VI	Review to commence on November 1

   This review schedule would result in public hearings to be conducted in June (for the May 1 review cycle) and December (for the November 1 review cycle). This schedule, in a practical sense, avoids public hearings in the western, mountainous counties during the months when our state is more likely to have adverse weather conditions, and similarly schedules public hearings in the eastern counties after the traditional Atlantic hurricane season has ended.

   The County Need Determination should be invoked when the county station deficit reaches a level of 10 or more stations, and all facilities operating in the county are operating at the **85%** utilization level. If there is no facility in the county (operational or CON approved), and the dialysis station deficit reaches 10 or more, the County Need Determination is equal to the station deficit.

3. We do recommend a change to the information reported in Table C, the Census of Home Dialysis Patients. Rather than report the number of dialysis patients served by a facility, by home dialysis modality, we believe that it would be more appropriate to report the number of home dialysis patients, by modality, by county of residence.

   The ESRD patient population of North Carolina continues to increase at an average annual rate of approximately 3.68% (five years ended December 31, 2016[2]). However, within the overall ESRD patient population, the home patient population is increasing at a rate of approximately 5.37%. And within the home ESRD patient population, our (Fresenius Medical Care) home hemodialysis patient population in North Carolina has increased at an average rate of greater than 12% over the past several years.

[2] The December 31, 2017 information is not yet available.

There are myriad reasons for the surge in the home hemodialysis patient population. Two of the more common reasons are changes in technology and nephrology physician interest. Technology has become more patient friendly in recent years. NxStg equipment has resulted in home dialysis patients performing more frequent dialysis, for shorter periods of time. The resultant patient outcomes are comparable to in-center dialysis programs, but offer the patient the advantage of performing dialysis on the patient schedule, not the dialysis facility schedule. Changes in technology have led to greater physician interest in prescribing home hemodialysis for those patients who might be better suited to home hemodialysis.

The growth in the home hemodialysis segment of the ESRD patient population warrants thorough evaluation by providers and by the State. The current reporting mechanism, Table C, does not thoroughly address the county of residence for the home hemodialysis patient populations. Some patients cross county lines to a home training program in a neighboring county.

Monitoring home hemodialysis patient populations by modality and county of residence will serve to highlight those areas where home hemodialysis populations are increasing at disparate rates. This would lead the SHCC, dialysis providers and nephrology physicians to further evaluate the reasons for such variances within the ESRD patient population.

4. At the April 13th meeting with providers, Agency Chief Ms. Frisone opened the door to discussion of eliminating the Facility Need Methodology in favor of a methodology of choice, to be explained by the CON applicant. This is an excellent idea. Other health services utilize various methodologies not prescribed by the Agency or the SMFP. Dialysis CON applicants should be allowed the same opportunity, with certain caveats. We offer the following suggestions related to elimination of the Facility Need Methodology:

   a. First, we believe that the current 80% utilization threshold should be raised, not lowered. We recommend that the Agency consider an **85%** utilization threshold as the standard, versus the current 80%.

      Within the meeting there seemed to be some underlying concern about counties (service areas) with inventories of surplus dialysis stations. Indeed, the January 2018 SDR reports that 57 of our 100 counties have surplus inventories ranging from a single station to 44 stations.

      Facilities have traditionally developed dialysis stations by way of the Facility Need Methodology. This methodology has relied upon the changes in a facility census over a six month period. Many facilities are serving patients from outside of the host county for the dialysis facility. Consequently, utilization in these facilities could be higher, and therefore the methodology generated more dialysis stations. It is our view that surplus inventories are not a significant concern, and that these stations are serving dialysis patients.

To the extent that the Agency does have a concern with regard to surplus stations, raising the standard to 85% will have some effect at reducing the number of CON applications filed. As an example, if the standard had been 85% for the most recent filings (January 2018 SDR, March 15 CON applications, April 1 review), Fresenius related facilities would have filed six fewer CON applications involving a total of 13 dialysis stations[3].

b. It is imperative that dialysis providers and facilities continue to have the opportunity to file for additional stations twice in each calendar year. As has already been noted within these comments, the ESRD patient population is increasing at a rate of 3.68%. Yet, the population of the state is increasing at a much lower rate. The US Census Bureau Quick Facts website reported the population estimates for July 1 of 2017 and 2016[4]. This information suggests the growth of the statewide population increased at 1.248%.

(July 1, 2017 – July 1, 2016) / July 1, 2016 = growth rate
(10,273,419 – 10,146,788) / 10,146,788 = 1.248%

The ESRD population for the same periods (June 30, 2016 and June 30, 2017) increased at a rate of 3.847%.

(June 30, 2017 – June 30, 2016) / June 30, 2016 = growth rate
(17,789 – 17,130) / 17,130 = 3.847%

The ESRD patient population of North Carolina increased at more than 300% of the state wide growth rate for the same period of time[5].

Elimination of the SDR and the Facility Need Methodology implies that CON applicants would be limited to a single filing each year. Given the significant difference in the growth rate of the ESRD patient population, we must have the opportunity to apply for additional dialysis stations twice in each calendar year. In this manner a facility would never be more than six months away from an opportunity to file for additional stations.

c. We support the concept of spreading the CON applications across the 12 month calendar. It has long been known that dialysis providers appear to file more CON applications than other regulated health services. For many years the filing date has been mid-March and mid-September, for the CON

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[3] This should not be read to say that Fresenius facilities applied for stations which were un-necessary. Based upon the current methodology, the performance standards at 10A NCAC 14C .2203, and our patient population, we believe that each of these applications was appropriate. The point of this discussion is to illustrate how increasing the performance standard could impact CON applications and the Agency overall.

[4] See Exhibit A.

[5] The June 30 2016 and 2017 ESRD data was reported in the January 2018 and 2017 SDR. We assume there is no significant difference between June 30 and July 1 of the same year.

application reviews commencing on April 1 and October 1. We agree that the Agency does see very many ESRD applications filed for these reviews, as our workload has been equally challenging leading up to the respective filing dates.

Distributing the filing dates over the course of the year, by Health Service Area (HSA), will certainly serve to more evenly distribute the Agency workload. Adopting such a change will likely result in changes to the CON Review Categories. We suggest the following:

Category D: New Dialysis Stations.

Category J: Change of scope and cost overruns (no change required).

Category K: Dialysis County Need Determinations

Category L: Relocation of existing certified dialysis stations pursuant to Policy ESRD-2; New kidney disease treatment centers for home hemodialysis or peritoneal dialysis services.

To that end, we have included an illustrative table[6] which distributes the filing dates throughout the year.

5. We recommend that CON applications seeking to establish new dialysis facilities by relocation of existing certified dialysis stations should be filed for the March, July, or November review cycle. The intent of this restriction is to further assist the Agency with distribution of its review workload. We recognize that this will actually limit these type of CON applications to only three filing opportunities each year.

6. We recommend that applications for Change of Scope or Cost Overrun CON applications should not be limited to any specific review cycle. Such applications are rarely filed. But more importantly, when such applications are filed it is highly likely that the related project will be delayed pending completion of review for the Change of Scope or Cost Overrun CON application. Such action does not promote access to care, but rather can impede access to care.

7. We recommend changes related to home therapies for both peritoneal dialysis and home hemodialysis.

   - The Agency should adopt performance standards for home dialysis programs, similar to those for the in-center dialysis facilities and codified at 10A NCAC 14C .2203(a) and .2203(b).

   - Dialysis stations dedicated to home hemodialysis training and support should be retained in the inventory of dialysis stations.

[6] See Exhibit B

- The Basic Principles of Chapter 14 of the SMFP should be changed such that home hemodialysis patients are counted toward station need determinations and station utilization.

Fresenius and related facilities are strong proponents of home therapies for dialysis patients. Home dialysis offers patients significant amounts of flexibility in scheduling dialysis treatment, and even in the location of performing the treatment.

In the April 13th meeting, Ms. Frisone noted that there is not a performance standard related to home dialysis. Further, the SMFP specifically excludes home patients from consideration for new dialysis stations[7]. This last point has created a conundrum for dialysis providers with regard to home hemodialysis.

While the Agency has largely approved development of home peritoneal dialysis programs at existing facilities, (and in some cases has actually approved development of peritoneal dialysis programs by CON application), the Agency practice has unintentionally contributed to conflict with regard to home hemodialysis programs, and has inferred that home hemodialysis training and support does require a dialysis station.

We don't believe the Agency intended to create such confusion. However, the Agency practice has established that home hemodialysis training and support programs, unlike the peritoneal dialysis training programs, do require a dialysis station, and therefore require CON application and approval. The conflict arises when considering that the SMFP specifically excludes home patients in determining need for new stations. While home hemodialysis patients are not counted toward the station need, a hemodialysis station is needed to provide the training for the home hemodialysis patient. The home hemodialysis patients are indeed utilizing dialysis station capacity.

We propose that the Agency adopt a performance standard specifically for home dialysis training and support programs. The following is offered as information for the Agency:

- Home training for the peritoneal dialysis patient requires approximately two weeks of training, and in some cases up to three weeks of training for the patient.

- Home training for the home hemodialysis patient requires approximately five weeks of training, and in some cases up to six weeks of training for the patient.

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[7] SMFP, Chapter 14, Basic Principles, point #5, *"Home patients will not be included in the determination of need for new stations. Home patients include those that receive hemodialysis or peritoneal dialysis."*

- Generally speaking, the home training rooms are also utilized by the home training clinic for "clinic days" when the home patients return to the facility for their monthly follow-up and visit with the nephrology physician and other members of the inter-disciplinary team (home training RN, dietitian, social worker, etc.)

Considering the variable training schedules for the home patients, and the need for the patient to meet with the inter-disciplinary team monthly, we recommend the following performance standard based upon typical utilization of the home training rooms, and a 75% utilization rate:

- *An applicant proposing to develop a new home training program for peritoneal dialysis shall document the need for the program based on a utilization of **12** patients per year at the end of the first year of operations of the program.*

- *An applicant proposing to develop a new home training program for hemodialysis shall document the need for the program based on a utilization of **six** patients per year at the end of the first year of operations of the program.*

- *An applicant proposing to develop a new home training program for both peritoneal dialysis and hemodialysis shall document the need for the program based on a utilization of **nine** patients per year, at the end of the first year of operations of the program.*

The above recommendations are based upon the following:

Peritoneal dialysis: A single patient can require up to three weeks of training. Therefore a training room could serve 17.33 patients in the course of a year. Using a 75% utilization rate, rounding down to the whole patient, we have calculated a need to serve 12 patients.

Hemodialysis: A single patient can require up to six weeks of training. Therefore a training room could serve 8.67 patients in the course of a year. Using the same 75% utilization rate, rounding down to the whole patient, we have calculated a need to serve six patients.

Dual modality home training: Based on 12 PD patients and six home hemodialysis patients, we have calculated a mix of nine patients as the minimum number of patients to be projected.

We further recommend that existing dialysis stations which are currently counted as a part of the facility station inventory should continue to be counted as a part of the facility station inventory, and ultimately the county inventory of dialysis stations.

As a final consideration for the home hemodialysis stations, we recommend that the SMFP be changed such that home hemodialysis patients are counted toward dialysis station utilization and need determinations. Given that the home hemodialysis patient is utilizing dialysis station capacity, it is not reasonable that these patients should not be counted toward station utilization and need determinations. To continue the current practice which requires the dialysis facility to essentially remove stations from in-center utilization, and dedicate these stations to the home hemodialysis patients, in essence unintentionally increases station utilization on the in-center stations, without allowing credit for the utilization by the home hemodialysis patient population.

As an example, consider the BMA Gastonia facility in Gaston County. This is a 39 station dialysis facility. Four of the stations are dedicated to the home hemodialysis patient population.

- BMA Gastonia in-center census on December 31, 2017 was 143 patients. Utilization in the July 2018 SDR will be reported as 91.7%, or 3.6667 patients per station.

- However, four stations are set aside for the home hemodialysis patient population. Thus, in a most practical sense, the in-center utilization at BMA Gastonia is a function of 143 patients dialyzing on 35 stations. Practical utilization is 102.14%, or 4.0857 patients per station.

- The facility was also serving 31 home hemodialysis patients as of December 31, 2017. Utilization by 31 patients on four dialysis stations is 258.33% or, 7.75 patients per station.

- In total, the BMA Gastonia facility was serving 174 hemodialysis patients (in-center and home) on 39 dialysis stations. Utilization should be calculated as 111.54%, or 4.4615 patients per station.

As another example, consider the BMA Lenoir facility in Caldwell County. This is currently a 34 station dialysis facility with one station dedicated to the home hemodialysis patient population.

- BMA Lenoir in-center census on December 31, 2017 was 122 patients. Utilization in the July 2018 SDR will be reported as 89.7%, or 3.5882 patients per station.

- However, one station is set aside for the home hemodialysis patient population. Thus, in a most practical sense, the in-center utilization at BMA Gastonia is a function of 122 patients dialyzing on 33 stations. Practical utilization is 92.42%, or 3.6970 patients per station.

- The facility was also serving three home hemodialysis patients as of December 31, 2017. Utilization by three patients on one dialysis stations is 75% or, 3.0 patients per station.

- In total, the BMA Lenoir facility was serving 125 hemodialysis patients (in-center and home) on 34 dialysis stations. Utilization should be calculated as 91.91%, or 3.6765 patients per station.

The above noted examples demonstrate that in facilities with large, or small home hemodialysis patient populations, the home hemodialysis patients do have effect upon the dialysis facility station utilization. These patients should be counted toward the need determinations.

8. We recommend that the isolation station(s) continue to be counted within the facility station inventory.

9. We offer the following recommended changes to the Basic Principles as listed in the SMFP, Chapter 14.

   a. We recommend that the SHCC amend Basic Principle #2 and remove the caveat, "to be cost effective and to assure quality of care". Dialysis providers operating in today's environment have no option but to be cost conscious. Medicare reimbursement rates have been bundled for several years, providing constant fiscal challenges to providers. Further, every facility is surveyed by the Acute and Home Care Branch, Licensure and Certification Section of DHSR, under the auspices of CMS. Quality of care is constantly monitored. A specific number of stations does not in and of itself promote sound fiscal operations or quality care. Providers promote both.

   b. We recommend that the SHCC amend Basic Principle #5. Home hemodialysis patients should be included in the determination of need for new stations. Home peritoneal dialysis patients should not be included in the determination of need for new stations.

   c. We recommend modifying Basic Principle #8 to eliminate items a. through g. The Agency has not established any bench marks for measuring specific facility performance, and there is no specific evidence that these items alone are indicators of quality care. Citing back to 10.a. above, all dialysis facilities in North Carolina are subject to survey by Licensure and Certification. Quality of care is measured, and reported by the Surveyor.

10. Finally, dialysis providers should be required to complete and submit the ESRD Data Collection Forms for the year ending December 31, within 75 days of year end. DHSR Healthcare Planning should make the ESRD Data Collection Forms available on line not later than December 1 of each year.

If you have any questions, or if I can be of further assistance, please call me.

Sincerely,

Jim Swann
Director, Certificate of Need

2 Attachments

1) Exhibit A, US Census Bureau Quick Facts
2) Exhibit B, Sample Schedule for Dialysis CON applications

Exhibit A

US Census Bureau Quick Facts

United States Census Bureau

QuickFacts
North Carolina

QuickFacts provides statistics for all states and counties, and for cities and towns with a ***population of 5,000 or more***.

Table

ALL TOPICS	North Carolina
Population estimates, July 1, 2017, (V2017)	**10,273,419**
Population estimates, July 1, 2016, (V2016)	**10,146,788**
PEOPLE	
Population	
Population estimates, July 1, 2017, (V2017)	**10,273,419**
Population estimates, July 1, 2016, (V2016)	**10,146,788**
Population estimates base, April 1, 2010, (V2017)	9,535,721
Population estimates base, April 1, 2010, (V2016)	9,535,688
Population, percent change - April 1, 2010 (estimates base) to July 1, 2017, (V2017)	7.7%
Population, percent change - April 1, 2010 (estimates base) to July 1, 2016, (V2016)	6.4%
Population, Census, April 1, 2010	9,535,483
Age and Sex	
Persons under 5 years, percent, July 1, 2016, (V2016)	6.0%
Persons under 5 years, percent, April 1, 2010	6.6%
Persons under 18 years, percent, July 1, 2016, (V2016)	22.7%
Persons under 18 years, percent, April 1, 2010	23.9%
Persons 65 years and over, percent, July 1, 2016, (V2016)	15.5%
Persons 65 years and over, percent, April 1, 2010	12.9%
Female persons, percent, July 1, 2016, (V2016)	51.4%
Female persons, percent, April 1, 2010	51.3%
Race and Hispanic Origin	
White alone, percent, July 1, 2016, (V2016) (a)	71.0%
Black or African American alone, percent, July 1, 2016, (V2016) (a)	22.2%
American Indian and Alaska Native alone, percent, July 1, 2016, (V2016) (a)	1.6%
Asian alone, percent, July 1, 2016, (V2016) (a)	2.9%
Native Hawaiian and Other Pacific Islander alone, percent, July 1, 2016, (V2016) (a)	0.1%
Two or More Races, percent, July 1, 2016, (V2016)	2.2%
Hispanic or Latino, percent, July 1, 2016, (V2016) (b)	9.2%
White alone, not Hispanic or Latino, percent, July 1, 2016, (V2016)	63.5%
Population Characteristics	
Veterans, 2012-2016	683,221
Foreign born persons, percent, 2012-2016	7.7%
Housing	
Housing units, July 1, 2016, (V2016)	4,540,498
Housing units, April 1, 2010	4,327,528
Owner-occupied housing unit rate, 2012-2016	64.8%
Median value of owner-occupied housing units, 2012-2016	$157,100
Median selected monthly owner costs -with a mortgage, 2012-2016	$1,243
Median selected monthly owner costs -without a mortgage, 2012-2016	$376
Median gross rent, 2012-2016	$816
Building permits, 2016	60,550
Families & Living Arrangements	
Households, 2012-2016	3,815,392
Persons per household, 2012-2016	2.54
Living in same house 1 year ago, percent of persons age 1 year+, 2012-2016	84.7%
Language other than English spoken at home, percent of persons age 5 years+, 2012-2016	11.3%
Education	
High school graduate or higher, percent of persons age 25 years+, 2012-2016	86.3%
Bachelor's degree or higher, percent of persons age 25 years+, 2012-2016	28.0%

Health	
With a disability, under age 65 years, percent, 2012-2016	9.7%
Persons without health insurance, under age 65 years, percent	▲ 12.2%
Economy	
In civilian labor force, total, percent of population age 16 years+, 2012-2016	61.5%
In civilian labor force, female, percent of population age 16 years+, 2012-2016	57.4%
Total accommodation and food services sales, 2012 ($1,000) (c)	18,622,258
Total health care and social assistance receipts/revenue, 2012 ($1,000) (c)	55,227,505
Total manufacturers shipments, 2012 ($1,000) (c)	202,344,646
Total merchant wholesaler sales, 2012 ($1,000) (c)	105,275,586
Total retail sales, 2012 ($1,000) (c)	120,691,007
Total retail sales per capita, 2012 (c)	$12,376
Transportation	
Mean travel time to work (minutes), workers age 16 years+, 2012-2016	24.1
Income & Poverty	
Median household income (in 2016 dollars), 2012-2016	$48,256
Per capita income in past 12 months (in 2016 dollars), 2012-2016	$26,779
Persons in poverty, percent	▲ 15.4%

BUSINESSES

Businesses	
Total employer establishments, 2015	223,209[1]
Total employment, 2015	3,670,284[1]
Total annual payroll, 2015 ($1,000)	164,936,258[1]
Total employment, percent change, 2014-2015	3.1%[1]
Total nonemployer establishments, 2015	722,639
All firms, 2012	805,985
Men-owned firms, 2012	435,677
Women-owned firms, 2012	287,058
Minority-owned firms, 2012	183,380
Nonminority-owned firms, 2012	603,182
Veteran-owned firms, 2012	86,571
Nonveteran-owned firms, 2012	684,743

GEOGRAPHY

Geography	
Population per square mile, 2010	196.1
Land area in square miles, 2010	48,617.91
FIPS Code	37

Value Notes

1. Includes data not distributed by county.

▲ This geographic level of poverty and health estimates is not comparable to other geographic levels of these estimates

Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable. Click the Quick Info ⓘ icon to the TABLE view to learn about sampling error.

The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). *Different vintage years of estimates are not comparable.*

Fact Notes

- **(a)** Includes persons reporting only one race
- **(b)** Hispanics may be of any race, so also are included in applicable race categories
- **(c)** Economic Census - Puerto Rico data are not comparable to U.S. Economic Census data

Value Flags

- **-** Either no or too few sample observations were available to compute an estimate, or a ratio of medians cannot be calculated because one or both of the median estimates falls in the lowest or upper ir distribution.
- **D** Suppressed to avoid disclosure of confidential information
- **F** Fewer than 25 firms
- **FN** Footnote on this item in place of data
- **NA** Not available
- **S** Suppressed; does not meet publication standards
- **X** Not applicable
- **Z** Value greater than zero but less than half unit of measure shown

QuickFacts data are derived from: Population Estimates, American Community Survey, Census of Population and Housing, Current Population Survey, Small Area Health Insurance Estimates, Small Area Income anc State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits.

No search results.

Exhibit B

DRAFT DIALYSIS CON Review Schedule

CON Beginning Review Date	HSA I, II, III	HSA IV, V, VI
January 1, 2019		
February 1, 2019	D (I only) J	D (I only) J
March 1, 2019	J L	J L
April 1, 2019	D (II only) J	D (II only) J
May 1, 2019	J K	J
June 1, 2019	D (III only) J	D (III only) J
July 1, 2019	J L	J L
August 1, 2019	D (I only) J	D (I only) J
September 1, 2019	J	J
October 1, 2019	D (II only) J	D (II only) J
November 1, 2019	J L	J K L
December 1, 2019	D (III only) J	D (III only) J