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VIA ELECTRONIC SUBMISSION – (Bronnakahle@house.mi.gov, kzubek@house.mi.gov)

May 12, 2021

Representative Bronna Kahle, Chairwoman
Committee on Health Policy
Michigan House of Representatives
124 North Capitol Avenue
Lansing, MI 48933

Re: House Bill 4659 (12:30 meeting 5/12/21)

Dear Madame Chair

DaVita Inc. (DaVita) appreciates the opportunity to submit comments regarding House Bill (HB) 4659, relating to electronic prescribing of prescription drugs. DaVita is a dialysis provider providing quality life-saving care to patients diagnosed with end stage kidney disease (ESKD). DaVita cares for over 6,000 Michigan residents through the 86 clinics that we operate in the state. As a healthcare provider, we recognize the extent of the opioid epidemic in our country and are supportive of policy initiatives aimed at making access to opioids and other prescription drugs safer for our patients and communities. We believe that legislation to strengthen and control the overall medication supply chain, including electronic prescribing, is part of a broader strategy to hold bad actors accountable, and we are supportive of these efforts. Accordingly, we commend Michigan for the action it has already taken in this area, and submit this letter in support of HB 4659's technical corrections to Michigan's electronic prescribing requirements scheduled to go into effect later this year.

I. Electronic Prescribing and Home Dialysis

As a dialysis provider, DaVita treats an incredibly fragile patient population – individuals with ESKD. Dialysis patients may receive in-center hemodialysis (ICHD) at a dialysis clinic or, increasingly, may choose to receive their dialysis treatments in their home through one of two modalities – peritoneal dialysis (PD) or home hemodialysis (HHD). DaVita has been a leader in home dialysis and currently serves over 29,000 home dialysis patients, including just over 1,000 home dialysis patients in Michigan. Regardless of the setting in which dialysis is provided, it is a life-

saving treatment that involves frequent dosing adjustments for multiple medications, many of which are administered intravenously as part of the dialysis treatment. These medications may include:

- Erythropoiesis Stimulating Agents (in DaVita facilities this is Epogen®; Epoetin alfa, Amgen, Thousand Oaks, CA);
- Iron (Venofer®; iron sucrose, American Regent, Shirley, NY);
- Activated Vitamin D (Hectoral®; doxercalciferol, Sanofi Renal, Bridgewater, NJ); and
- Heparin (heparin injection, generic).

On occasion, intravenous (IV) or intraperitoneal (IP) antibiotics may also be required to address instances of infection. In no case, however, do these medications include controlled substances, as dialysis care does not involve the administration or prescription of controlled substances.

The physician's order for home dialysis treatment includes these medications, which the patient is trained to administer intravenously or in an intraperitoneal manner. Then patient receives the ordered medications from either a third party pharmacy or, in some instances, from DaVita's own stock. This allows the patient to maintain a supply of necessary medications at home in order to adjust the dosage depending on changing needs as managed through physician-ordered protocols that are responsive to changes in labs and the patient's condition. Subjecting these medications to the electronic prescribing requirement could undermine patient safety by delaying administration, result in patient harm, and otherwise undermine the quality of their home dialysis care.

For example, Epogen (administered to prevent transfusion and adverse cardiovascular events) and Hectoral (administered to prevent mineral bone disease, hypercalcemia, hyperphosphatemia, and vascular calcification) both come in many available doses – with no one dose being appropriate for a patient every single time. These drugs are managed by protocol, which allows dosages to be adjusted according to laboratory results. Subjecting these medications to an electronic prescribing requirement would render management by protocol impossible, as it could result in a home dialysis patient not having the right dosage of the medication available to them in their home supply.

Another example of potential patient harm is with respect to IV/IP antibiotics. According to the International Society for Peritoneal Dialysis, 1.4% of patients on the PD modality get a peritonitis infection each month. Under current circumstances, patients with suspected bloodstream infection are administered empiric antibiotics. If blood or peritoneal effluent cultures prove negative, as they do in approximately 20% - 30% of cases, empiric antibiotics may be discontinued. If effluent cultures of a PD patient are positive, antibiotics are adjusted according to the organism's reported sensitivity profile. Approximately half of those with confirmed infection are admitted to the hospital. If IV/IP antibiotics are not available in the dialysis provider's own stock, for purposes of providing to home patients – as would be the case if electronic prescribing regulations were extended to medications that are administered in connection with

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home dialysis treatments, then most patients with suspected bloodstream or peritonitis infection would likely be transported immediately to the hospital for admission and treatment. For those patients currently managed without hospitalization, the result would create new healthcare costs with no improvement to population health. However, this undesired effect is not merely a matter of raising costs to the healthcare system. Adult dialysis patients, when presented with the question, how much of your remaining lifespan would you trade in order to stay out of the hospital, answer an astounding seven (7) months. Avoiding hospitalization is a central issue in preserving quality of life for our patients.

II. Conclusion

DaVita is supportive of Michigan's efforts to improve the safety of the medication supply chain, including through an electronic prescribing requirement. However, in order to avoid potential disruption to home dialysis treatments, we support the additional exclusion for home dialysis medications proposed in HB 4695. We appreciate your consideration of our comments and welcome the opportunity to discuss this issue further.

Sincerely,

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Impact of E-Prescribing on Dialysis Treatments

In brief

Extension of an e-prescribe requirement to intravenous medications administered In-Center Hemodialysis facilities ('ICHD') or Home dialysis programs ('Home') would delay treatment for potentially life-threatening conditions, increase the risk of medication error and infection, and present a barrier to safe and timely transitions of care, and would thereby pose a major risk to patient safety in a complex, chronically ill and highly vulnerable patient population. Also, DaVita does not administer narcotics in our facilities.

Background: What makes a dialysis facility different from other healthcare settings?

The combination of a small patient population; the magnitude and complexity of the population disease burden; the intensity of disease management across biopsychosocial dimensions and over months and years for each patient; and the continuous performance of high-volume, high-risk procedures distinguishes the freestanding dialysis center from inpatient and other outpatient healthcare settings.

A mid-sized dialysis facility may have no more than 100 ICHD patients and 30 Home patients undergoing treatment. However, ICHD patients come to the treatment facility, treat, then return home, three times a week, week in and week out. Home patients show up weekly for injections or to be trained to self-administer at home and obtain their medication supplies from a pharmacy. In a month, a 100 ICHD & 30 Home patients will undergo approximately 1,300 ICHD and 3,000 Home dialysis treatments. During their collective 4,600 ICHD & 72,000 Home patient-hours of treatment in that month, this small, exquisitely fragile patient population will have 5,600 ICHD and Home weights recorded before and after dialysis or completed and brought into the clinic, and will have at least 12,200 ICHD and Home blood pressures recorded before during and after each procedure. ICHD patients undergo cannulation 2,200 times using large bore needles to make possible the circulation of over 100,000 liters of blood that will pass through tubing and dialyzers before returning to the patient; their blood, while in transit through their dialyzers, will be cleaned by 160,000 liters of dialysate which is formulated within each facility then delivered safely to each patient according to a patient-specific prescription. ICHD and Home patients receive IV medications to manage anemia and mineral bone disease in order to achieve CMS-mandated clinical performance measures. ICHD patients will be administered heparin to achieve anticoagulation of the extracorporeal circuit during each dialysis session; and, they will have approximately 3,000 different blood tests drawn, analyzed, reported, and reviewed.

Intravenous agents administered in outpatient ICHD and Home facilities include erythropoiesis stimulating agents (in DaVita facilities this is Epogen®; Epoetin alfa, Amgen, Thousand Oaks, CA), iron (Venofer®; iron sucrose, American Regent, Shirley, NY); activated vitamin D (Hectoral®; doxercalciferol, Sanofi Renal, Bridgewater, NJ), and heparin (heparin injection, generic). Epogen, Hectoral and heparin are provided to or administered to most if not all patients at each treatment. In DaVita facilities, IV iron is administered or provided for home administration weekly in most patients.

The magnitude and complexity of the population disease burden, the underlying risk of the dialysis procedure, and the potential to acquire bloodstream bacterial infection or transmit blood borne virus, together render the maintenance of patient safety a paramount organizing principle of every dialysis facility. Extensive policy and procedure (eight hundred and fifty five pages in DaVita facilities); oversight through a CMS-defined quality assurance, process improvement, and governance process (Conditions for Coverage of ESRD Facilities); dedicated medication storage and preparation areas; selection of vial sizes and syringes; and, computer-assisted workflow solutions, clinical pathways, and protocols are all

designed to reduce the potential for harm. By requiring all IV medications to be ordered via ePrescribe, extending ePrescribe regulations to IV medications in dialysis facilities would place medication ordering, acquisition, storage, preparation and administration outside these existing, extensive and robust safety systems. Foreseeable adverse consequences on patient safety would include the following:

- *Direct patient harm.*
    - **Epogen (avoidable transfusion and adverse cardiovascular events):** Patients can receive any of 95 possible doses for Epogen. No one dose fits all patients. Nor can each patient be assigned a single, individualized dose: rather, as the patient's condition changes, doses are continuously adjusted at weekly to monthly intervals. Failure to adjust doses may risk severe anemia and red cell transfusion from under-treatment or cardiovascular events including stroke or myocardial infarction from overtreatment. For the vast majority of their patients, physicians choose to use computer-assisted protocols, which uses each patient's electronic record to assess recent trends in blood hemoglobin against current Epogen dose, matches that data set to the physician's order for how to adjust Epogen under that specific condition, and provides a per-protocol order for consideration. Once accepted, the prescribed dose is recorded electronically and sets in motion a series of steps that assure that the patient receives or self-administers the prescribed dose from the right vial with the correct syringe; for ICHD, that each syringe is personally and correctly labelled for each patient; that the patient receives the ordered dose as prescribed; and, that the Hb is again drawn after the correct interval so that the result can again be assessed, doses adjusted, and the process renewed. Computer-assisted protocols reduce the potential for medication error, minimize treatment risks, and provide the evidence needed to continuously improve. Extending an ePrescribe requirement to Epogen in the dialysis facility, by uncoupling medication ordering, acquisition, storage, preparation, and administration from the current electronic clinical applications, would render per-protocol management impossible.
    - **Hectoral (mineral bone disease, hypercalcemia, hyperphosphatemia, vascular calcification).** Like Epogen, Hectoral comes in many available doses; no one size fits all; doses must be adjusted according to laboratory results for each patient; and, physicians prefer to manage the vast majority of their patients by protocol. Under-treatment risks weakening of the bones (mineral bone disease) from secondary hyperparathyroidism whereas overtreatment risks hypercalcemia, hyperphosphatemia, and progressive vascular calcification. Extending an ePrescribe requirement to Hectoral in the dialysis facility, by uncoupling medication ordering, acquisition, storage, preparation, and administration from the current electronic clinical applications, would render per-protocol management impossible, raising the risks of both under- and over-treatment.
    - **Venofer (iron deficiency, iron overload).** Intravenous iron is provided to avoid iron deficiency and to minimize potentially hazardous doses of erythropoiesis-stimulating agents. Oral iron agents are not an effective option in dialysis patients. To prevent risks of both under- or over-treatment, physicians prescribe Venofer (again, the vast majority by protocol) according to rules that link dose adjustment to laboratory results obtained on a regular basis; using protocols, physicians specify which iron status tests to obtain and how often, and precisely when to start Venofer, how much to give and how often, and when to stop or hold iron therapy, according to test results. In the patient with primary or secondary erythrocytosis, provision of IV iron can result in stroke or death due to uncontrolled red cell production: the protocols alert caregivers to results that

would identify such patients and so that further iron therapy can be withheld. Extending an ePrescribe requirement to Venofer in the dialysis facility, by uncoupling medication ordering, acquisition, storage, preparation, and administration from the current electronic clinical applications, would render per-protocol management impossible, raising the potential for harm to patients.

- **Heparin (thrombosis of the extracorporeal circuit with resulting blood loss, or over-anticoagulation with pathologic bleeding).** All patients are candidates for systemic heparin anticoagulation during the course of the dialysis procedure, to prevent thrombosis of the tubing and dialyzer or fibrin formation in the Peritoneal catheter, which can prevent use of the catheter resulting in the inability to perform therapy at Home until resolved, which results in early termination of the procedure and significant loss of the patient's blood. The vast majority of patients receive heparin on each treatment. Doses are adjusted according to changes in the patient's weight and the physician's assessment of bleeding risk. Extending an ePrescribe requirement to each order for heparin would discourage dose adjustment, raising the potential for harm to patients.
- **IV/IP antibiotics (untreated bloodstream infection, avoidable hospitalization).** An episode of bloodstream infection for ICHD patients, with fever, chills or hypotension, is suspected in 4-5% of ICHD patients each month. Home patients, according to the International Society for Peritoneal Dialysis ('PD'), 1.4% get a peritonitis infection each month. Under current circumstances, patients with suspected bloodstream infection are administered empiric antibiotics. If blood or peritoneal effluent cultures prove negative, as they do in approximately 20% - 30% of cases, empiric antibiotics may be discontinued. If blood cultures for ICHD or peritoneal effluent for Home prove positive, antibiotics are adjusted according to the organism's reported sensitivity profile. Approximately half of those with confirmed infection are admitted to the hospital. If IV/IP antibiotics were not available in the facility, as would be the case if ePrescribe regulations were extended to dialysis facilities, then most patients with suspected bloodstream or peritonitis infection would likely be transported immediately to the hospital for admission and treatment. For those patients currently managed without hospitalization, the result would create new healthcare costs with no improvement to population health. But this undesired effect is not merely a matter of raising costs to the healthcare system. Adult dialysis patients, when presented with the question, how much of your remaining lifespan would you trade in order to stay out of the hospital, answer an astounding seven (7) months. Avoiding hospitalization is a central issue in preserving quality of life for our patients.

- *Risk of transmission of bloodborne viral pathogens.* According to the CDC, outbreaks of hepatitis C in dialysis facilities have been linked to preparation of IV/IP medications, particularly those from multidose vials. Under current circumstances, a single multidose vial is exposed to potential contamination only briefly, since needed doses for multiple patients can be drawn and the vial emptied on a single shift or group of patients. If each patient must have his or her set of IV/IP agent vials, as would be required should ePrescribe be applied to dialysis facilities, then each multidose vial (those for Epogen, Hectoral and Heparin) will be labelled and stored on site, and will have to be repeatedly exposed to potential contamination at each preparation, until the vial is either emptied or discarded. This would be a significant, new, predictable and avoidable hazard.
- *Delay in treatment resulting in harm to new or existing patients; discouraging travel.* Because each facility stocks sufficient IV/IP medication for current use by any patient in the ICHD facility

or Home program, delays in dose adjustment, providing new medications in existing patients, or initiating treatment for patients new to the facility is accomplished without delay. Over forty thousand ICHD DaVita patients dialyzed each year at at least one facility that is not their home facility. Some patients do so to travel for pleasure or for work, while others miss treatment at one facility (often for intercurrent illness or access thrombosis) but can be dialyzed the following day at another facility with an opening. Extending ePrescribe regulations to dialysis facilities, by precluding use of medications in facility inventory, would make it impossible to provide timely care to patients new to a facility, posing significant risk of harm on the one hand and detracting substantially from quality of life on the other. However, one of the benefits of Home is the ability to travel.

- *Delay in implementing critical transitions of care.* Patients transitioning back to the facility or their home after hospitalization frequently return with new or adjusted prescriptions for IV/IP medications. For example, patients who were admitted for treatment of bloodstream or peritonitis infection, or whose hospital course was complicated by systemic infection, return to the facility with new IV/IP antibiotic orders. Currently these patients can receive their initial antibiotics without delay, using agents stocked in the facility. Extending ePrescribe regulations to dialysis facilities would make it impossible to provide safe and timely transitions of care to those patients returning from hospitalization, posing significant risk of harm and introducing a new point of potential process failure.
- *Inability to provide safe care during large-scale emergencies.* Hurricanes and floods (Hurricane Sandy, for example), or more local emergencies, including building fires or municipal water supply contamination, force the immediate closure of hemodialysis facilities and relocation of their patients to new facilities. Under current circumstances, these suddenly-relocated patients can continue to safely receive their IV/IP agents as prescribed in their new facilities, without interruption. Extending ePrescribe regulations to dialysis facilities would make it impossible to provide timely IV medications to patients relocated after sudden closure of their home facility, posing significant risk of harm.
- *Removal of formulary management barriers to unsafe prescribing practice.* Formulary management tools play a critical role in standardizing around best practices, reducing the potential for medication error (for example: most facilities will have only one vial size and concentration for each IV/IP agent), and ensuring antibiotic stewardship within any healthcare setting. In the high-volume, high-risk setting of the dialysis facility, robust formulary management tools are tightly integrated into computerized clinical applications, inventory management, and medication preparation logistics. Extending ePrescribe regulations to dialysis facilities would make it possible to bypass these well established, highly effective tools for patient safety.