

Summary of Dialysis Facility Surveys in Maryland 2012-2016.

A Report for the Maryland Commission on Kidney Disease

May 3rd, 2018

Ying-Che Huang, MD

Bernard G. Jaar, MD, MPH

Mission of the Maryland Commission on Kidney Disease

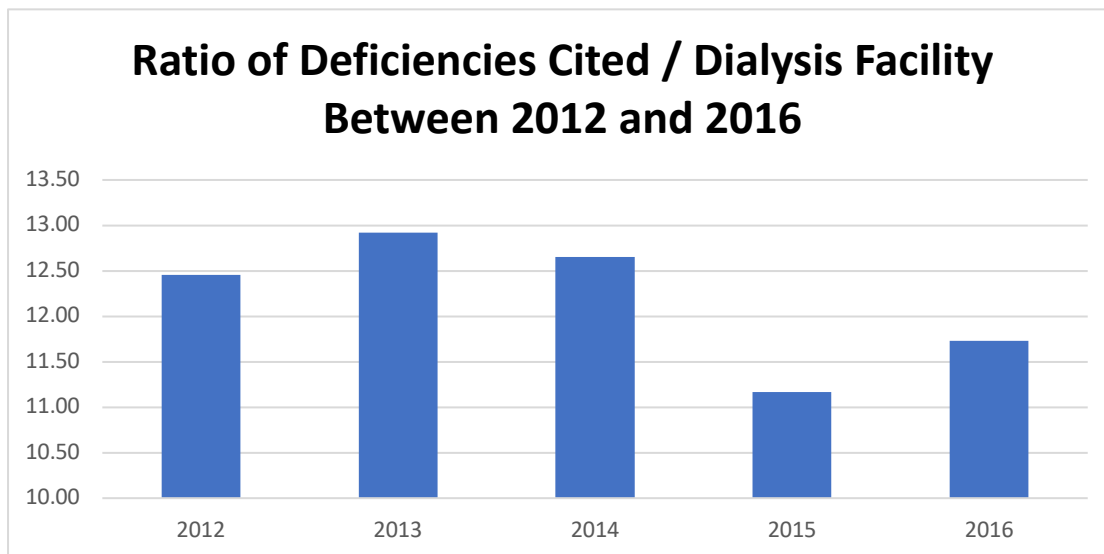
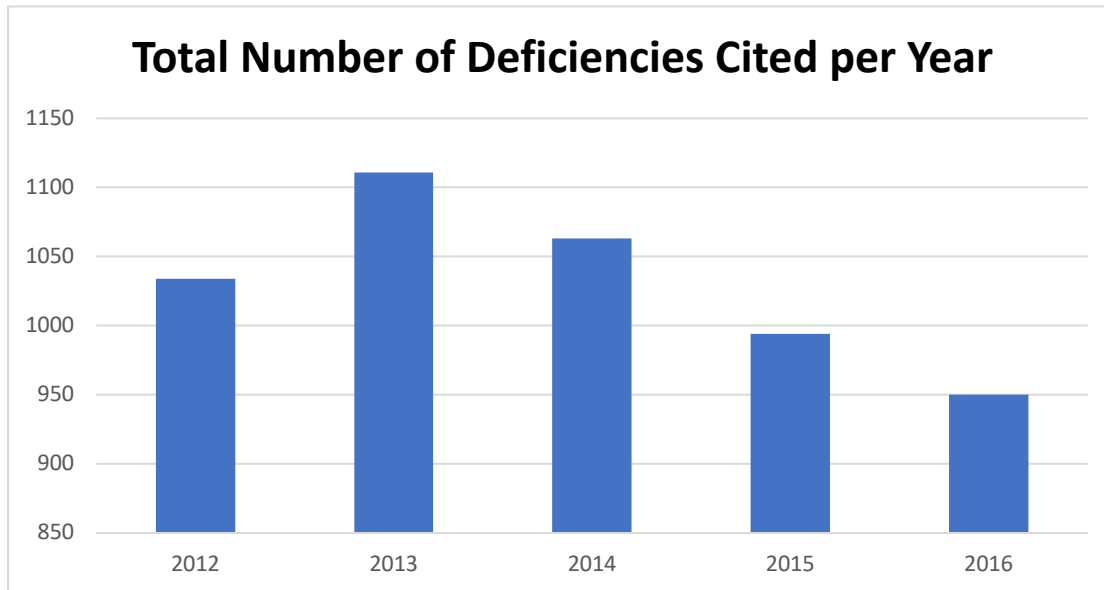
The Mission of the Maryland Commission on Kidney Disease is to protect the citizens of Maryland and to promote quality health care in the field of nephrology and transplantation by:

- Certifying dialysis and transplant centers
- Receiving and resolving complaints from the public, patients, courts, employers, employees, insurance companies, other centers regarding the health care providers in the center who may have violated the Commission's law (Annotated Code of Maryland, Health General Article, Title 13) and its regulations found at COMAR 10.30.01; and
- Setting standards for the practice of chronic dialysis and transplantation that reflect new and emergent developments in the practice of chronic dialysis and kidney transplantation through regulations and legislation.

Content

CHAPTER 1: OVERALL TREND IN DIALYSIS FACILITY DEFICIENCIES BETWEEN 2012-2016	3
CHAPTER 2: CATEGORIES OF DEFICIENCIES	5
CHAPTER 3: INFECTION CONTROL	6
CHAPTER 4: WATER AND DIALYSATE QUALITY	10
CHAPTER 5: PHYSICAL ENVIRONMENT.....	14
CHAPTER 6: PATIENTS' RIGHTS.....	17
CHAPTER 7: PATIENT ASSESSMENT.....	19
CHAPTER 8: PATIENT PLAN OF CARE	21
CHAPTER 9: CARE AT HOME	24
CHAPTER 10: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT	27
CHAPTER 11: LABORATORY/AFFILIATION GUIDELINES	30
CHAPTER 12 : PERSONNEL QUALIFICATIONS / STAFFING.....	32
CHAPTER 13: RESPONSIBILITIES OF THE MEDICAL DIRECTOR.....	34
CHAPTER 14: MEDICAL RECORDS	36
CHAPTER 15: GOVERNANCE	38
CHAPTER 16: CONCLUSION.....	40

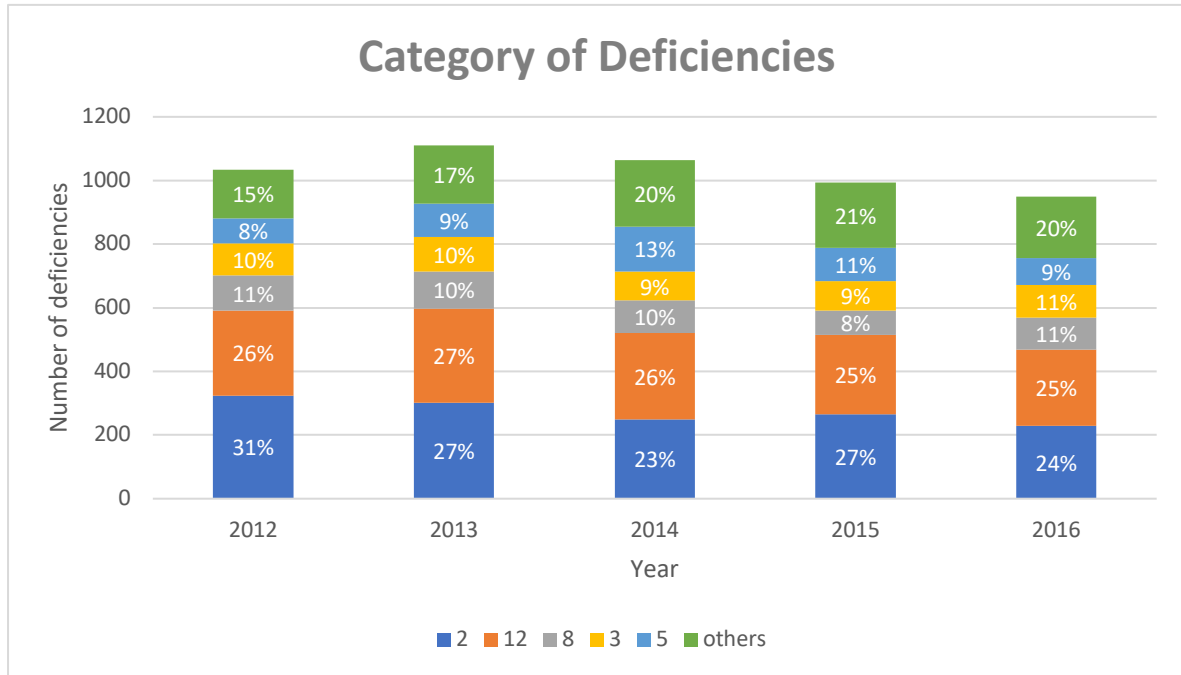
Chapter 1: Overall trend in dialysis facility deficiencies between 2012-2016



Year	2012	2013	2014	2015	2016
Total number of Deficiencies Cited per year	1034	1111	1063	994	950
Number of Dialysis Facilities Surveyed	83	86	84	89	81
Ratio of Deficiencies/ Facility	12.46	12.92	12.65	11.17	11.73

Between 2012 and 2016, more than 80 dialysis facilities were surveyed each year. Also, every year, there were more than 900 citations. An average, there were about 12 citations per facility every year. In 2013, we saw the highest number of citations to 1,111 with a ratio of almost 13 citations per facility. In 2016, we saw the lowest number of citations at 950 but also the lowest number of facilities surveyed at 81. However, 2015, showed the best year in term of less citations with a ratio of citations per facility at about 11.

Chapter 2: Categories of Deficiencies

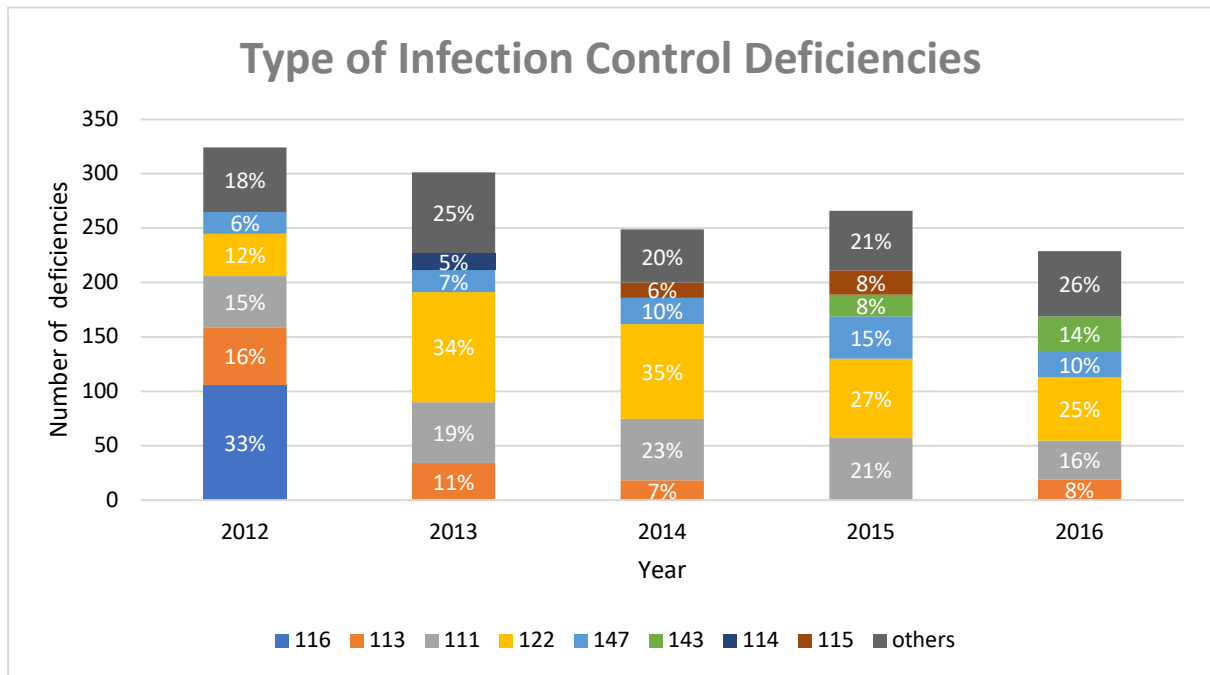


The Top 5 categories of deficiencies (2, 12, 8, 3, 5) remain the same between 2012 and 2016 in dialysis facilities in the State of Maryland.

Index Definition of Categories:

- 2: Infection Control
- 3: Water and Dialysate Quality
- 5: Physical Environment
- 8: Patient Plan of Care
- 12: Personnel Qualifications/ Staffing
- Others: Compliance with Federal, State and Local Laws and Regulations, Reuse of Hemodialyze and Bloodlines, Patients Rights, Patient Assessment, Care at Home, Quality Assessment and Performance Improvement, Laboratory/Affiliation Guidelines, Responsibilities of the Medical Director, Medical Records, Governance

Chapter 3: Infection Control



The bar chart above showed the top 5 and the other deficiencies in the infection control category between 2012 and 2016. By and large, the infection control issues improved over the years of follow-up but there was a similar deficiency pattern of infection control in these 5 years. V116 was very high in 2012, but it showed a significant improvement in the following year. V113, V111, V122 and V147 did not show significant changes during the 5 years of data analyzed.

We need to keep in mind that deficiencies that only showed in 1 or 2 years but are no longer part of the above chart in the subsequent years, does not mean that these deficiencies are not important but rather that they no longer in the top 5 deficiencies cited.

Chapter 3: Infection Control

Index Definition of Deficiencies:

- **V111** states - The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.
- **V113** states - CDC RR-5 as Adopted by Reference 42 CFR 494.30 (a)(1)(i)
Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. **Interpretive Guidance states** - Because exposure to blood and potentially contaminated items can be routinely anticipated during hemodialysis, gloves are required whenever caring for a patient or touching the patient's equipment. Gloves must be provided to patients and visitors if these individuals assist with procedures which risk exposure to blood or body fluids, such as when self-cannulating or holding access sites post treatment to achieve hemostasis. In addition, a new pair of clean gloves must be used each time for access site care, vascular access cannulation, administration of parenteral medications or to perform invasive procedures. The intention is to ensure that clean gloves which have not previously touched potentially contaminated surfaces are in use whenever there is a risk for cross contamination to a patient's blood stream to occur.
- **V114** states - CDC RR-5 as Adopted by Reference 42 CFR 494.30 (a)(1)(i)
A sufficient number of sinks with warm water and soap should be available to facilitate hand washing. **Interpretive Guidance states** - A "sufficient number" means that sinks are easily accessible and readily available in the patient treatment area and in other appropriate areas such as the reuse room, medication area, home training room, and isolation area/room to meet the needs of the staff and patients. Sinks must be plumbed with both hot and cold water; if the flow of water is started through motion detection, adjustments to the system must assure that warm water is available to encourage staff to wash their hands according to CDC recommendations (see V113). Handwashing sinks should be dedicated only for handwashing purposes and should remain clean. Avoid placing, cleaning, or draining used items in handwashing sinks. Used or contaminated items should be handled in designated utility sinks. The facility should have a sink available for patients to wash their access sites prior to treatment and their hands after treatment. This sink may also be used by staff for handwashing. Soap and a supply of paper towels protected from contamination must be available at each sink.

- **V115** states - CDC RR-5 as Adopted by Reference 42 CFR 494.30 (a)(1)(i)
Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.
- **V116** states - Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.
 - Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.
 - Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.
- **V122** Interpretive Guidance states - In hemodialysis units, cleaning and disinfection procedures during patient changeover are particularly prone to error and contribute to risk of cross-contamination if correct procedures are not observed. At the end of each dialysis treatment, all surfaces without visible blood should be cleaned following the low level disinfection protocol using soap, detergent or detergent germicide. For visible blood, the intermediate-level disinfection protocol must be followed, which requires the area be immediately cleaned with a cloth soaked with tuberculocidal disinfectant or 1:100 dilution of bleach (300-600 mg/L free chlorine), following the manufacturer's direction for contact time. Gloves must be worn, and the used cloth placed into a leak proof container. After cleaning up all visible blood, a disinfectant must be applied a second time using a new cloth or towel. No patient should be at the station during this time.
 - At the end of each patient treatment, the staff should clean and disinfect the dialysis station. Special attention should be given to cleaning control panels on the dialysis machines, the treatment chairs and other surfaces that are frequently touched and potentially contaminated with patients' blood. The staff should discard all fluids and clean and disinfect all surfaces of the containers associated with the prime waste (including containers attached to the machines) after each treatment.
- **V143** Interpretive Guidance states - The facility must have a mechanism in place to ensure expired medications are not available for use. Opened multiple-dose vials should

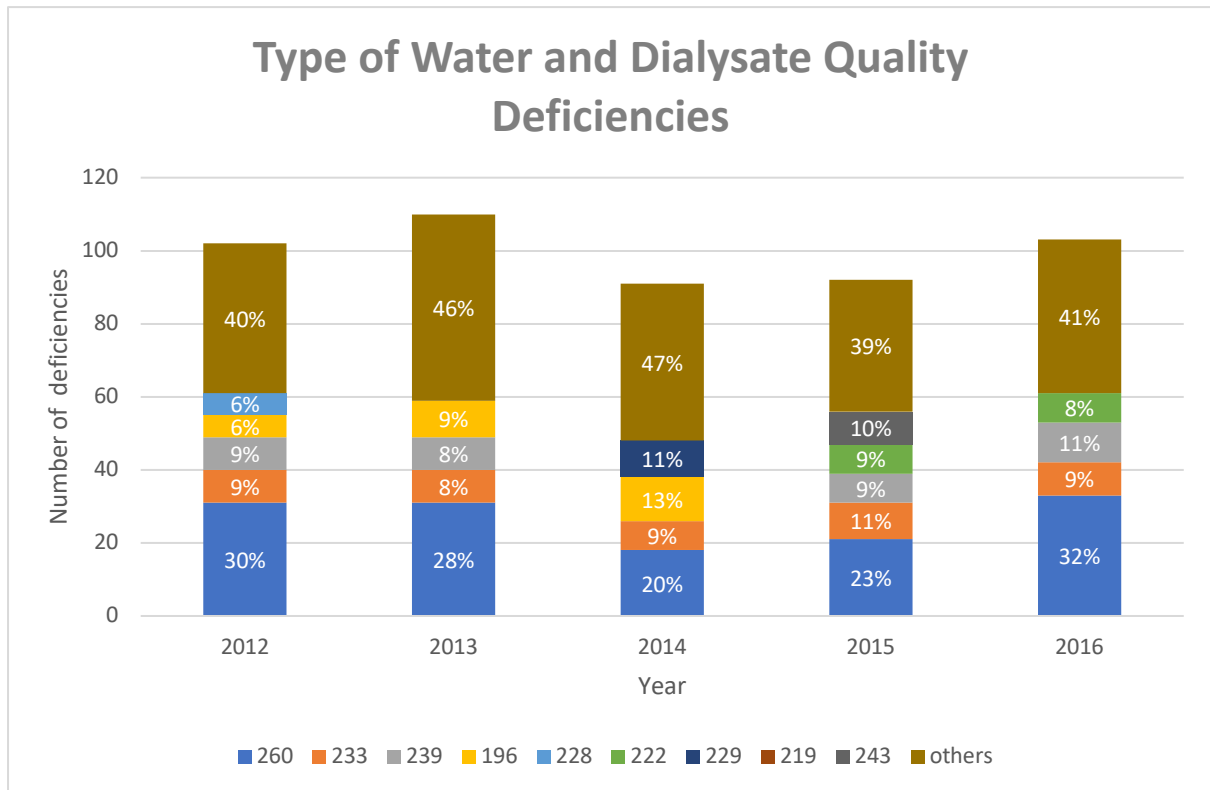
be handled aseptically and used and discarded in accordance with the manufacturer's set time frames and/or other accepted standards for use (e.g., US Pharmacopeia). Staff preparing medications should clean the septum of any multi-use vial with alcohol before inserting the needle and the injection port before using the port to administer a medication.

- Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules;

- **V147** Interpretive Guidance states - Facility staff should follow guidance from the NKF KDOQI Vascular Access Guideline (2006), which states "Airborne contaminants from both patients and staff are prevented best by the use of surgical masks when the catheter lumens or exit site are exposed. Wearing clean gloves and avoiding touching exposed surfaces further decreases the risk for infection. Aseptic technique includes minimizing the time that the catheter lumens or exit site are exposed."

- The CDC lists the two most common routes of catheter infection as (1) migration of skin organisms through the insertion site and into the cutaneous catheter tract resulting in colonization of the catheter tip; and (2) contamination of the hub, resulting in intraluminal colonization of the catheter. The initiation and termination of the dialysis process and manipulation and tension on the catheter provide frequent opportunity for such contamination. Minimizing the use of intravascular catheters and protection of the insertion site and the catheter hub from contamination through education and training about rigorous care is important in reducing catheter-related infections.

Chapter 4: Water and Dialysate Quality



The bar chart above showed the top 4 and the other deficiencies in the water and dialysate quality category between 2012 and 2016. By and large, the total number of the water and dialysate quality deficiencies did not show great changes over the years of follow-up and revealed a similar deficiency pattern in these 5 years. V260 remained the leading deficiency cited in this category between 2012 and 2016. On the other hand, V196 was among the top 4 in 2012-14, but it showed improvement in the subsequent 2 years. V233, V239 remained in the top 4 deficiencies cited between 2012 and 2016.

Chapter 4: Water and Dialysate Quality

Index Definition of Deficiencies:

- **V196** Interpretive Guidance - A.6.2.5 Carbon adsorption
The recommendation that the water purification system should operate for at least 15 minutes before samples are drawn is to guard against inadvertently sampling water that has been in the bed for an extended period.
- **V219** Interpretive Guidance States - ANSI/AAMI RD52:20047 Strategies for bacterial control7.1 General. The strategy for controlling the proliferation of microorganisms in hemodialysis systems primarily involves proper system design and operation, and regular disinfection of water treatment system and hemodialysis machines. A key concept in ensuring compliance with water bacteriology standards is that disinfection schedules should be designed to prevent bacterial proliferation, rather than being designed to eliminate bacteria once they have proliferated to an unacceptable level (i.e., above the action level). With this strategy, monitoring levels of bacteria and endotoxin serves to demonstrate that the disinfection program is effective, not to indicate when disinfection should be performed. Gram-negative water bacteria, their associated lipopolysaccharides (bacterial endotoxins), and nontuberculous mycobacteria (NTM) most frequently come from the community water supply, and levels of those bacteria can be amplified depending on the water treatment system, dialysate distribution system, type of dialysis machine, and method of disinfection.
- **V222** states - NSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a)5.4 Concentrate preparation 5.4.3 Bulk storage tanks (acid concentrate): safety controls Procedures should be in place to control the transfer of the acid concentrate from the delivery container to the storage tank to prevent the inadvertent mixing of different concentrate formulations. If possible, the tank and associated plumbing should form an integral system to prevent contamination of the acid concentrate. The storage tanks and inlet and outlet connections, if remote from the tank, should be secure and labeled clearly.
- **V228** states - ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a)5.4.4.1 Mixing systems: labeling Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine.
- **V229** states - ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR

494.40 (a) 5.4.4.1 Mixing systems: perm record/verification testing In addition to container labeling, there should be permanent records of batches produced. These records should include the concentrate formula produced, the volume of the batch, the lot numbers of powdered concentrate packages, the manufacturer of the powdered concentrate, the date and time of mixing, any test results, the person performing the mixing, the person verifying mixing and test results, and the expiration date (if applicable).

- **V233** Interpretive Guidance states - Bicarbonate concentrates must be used or discarded within the manufacturer's timelines, if these are available. If facility staff members combine bicarbonate concentrate from partially used jugs, there must be some system to ensure the concentrate is not kept past the maximum storage time of the oldest portion. For example, if the facility policy is to discard all unused concentrate at the end of each treatment day, combining jugs during the day would not exceed the limit if the allowable storage time was at least one day or 24 hours. If the facility policy allows carryover of unused concentrate to the following day, there could be potential for that time limit to be exceeded should the contents of jugs (which may have been mixed at various times) be combined.

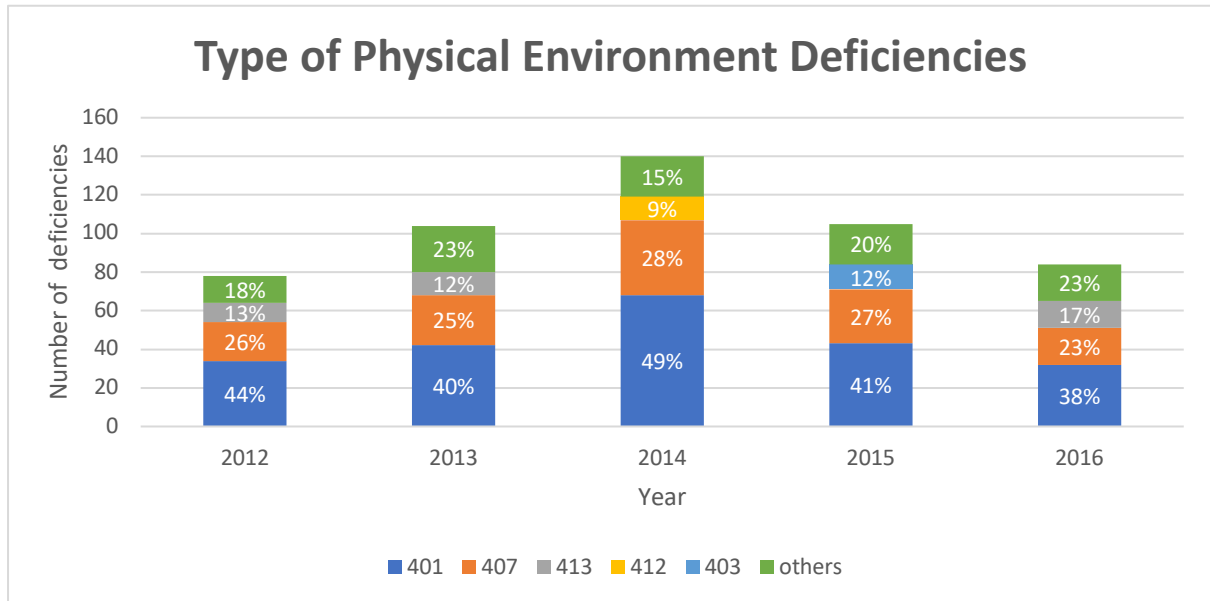
-Additional Guidance- Central delivery systems should be cleared of bicarbonate solution at some point during the treatment day and rinsed clear. Generally this is done at the end of the treatment day.

- **V239** states - ...6.5 Concentrate distribution: The interval between disinfection should not exceed 1 week. If the manufacturer does not supply disinfection procedures, the user must develop and validate a disinfection protocol.
- **V243** states - ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a)6.5 Concentrate distribution: bicarb jugs rinsed daily/stored dry
Bicarbonate concentrate jugs should be rinsed with treated water and stored inverted at the end of each treatment day. Pick-up tubes should also be rinsed with treated water and allowed to air dry at the end of each treatment day.
- **V260** states - ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 9 Personnel: training program/periodic audits A training program that includes quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues is mandatory.

-Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer.

- The training should be specific to the functions performed (i.e., mixing, disinfection, maintenance, and repairs).
- Periodic audits of the operators' compliance with procedures should be performed.
- The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.

Chapter 5: Physical Environment



The bar chart above showed the top 3 and the other deficiencies in the physical and environment category between 2012 and 2016. By and large, we see the highest total number of physical and environment deficiencies in 2014 but with improvement in the following 2 years. The type of deficiency pattern is similar in these 5 years. V401, V407 remained in the top 2 deficiencies cited between 2012 and 2016.

Chapter 5: Physical Environment

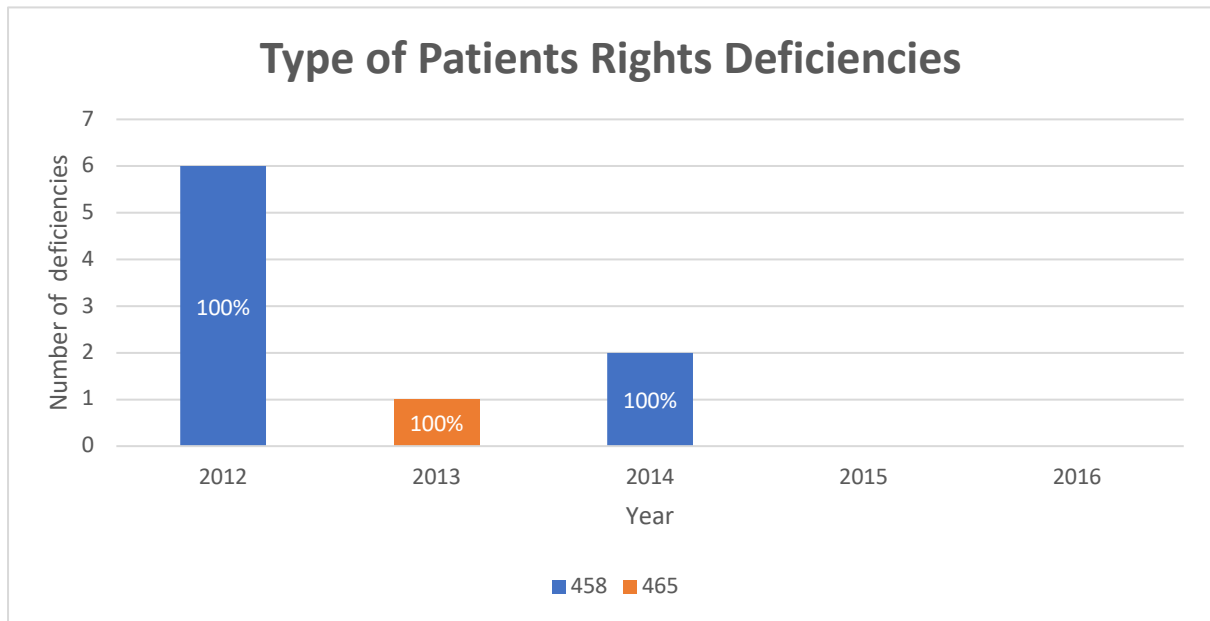
Index Definition of Deficiencies:

- **V401** states - The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional and comfortable treatment environment. Interpretive Guidance states - “Safe environment” means that there are no obstacles which would present risks for trips and falls, such as loose floor tiles; no areas that would pose infection control risks, such as broken work surfaces; and no outside doors that remain propped open allowing entry of unauthorized individuals, insects, or animals or creating a hazard in the event of fire.
- **V403** states - (b) Standard: Equipment maintenance. The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer’s recommendations. Interpretive Guidance - ...Staff must operate and maintain the equipment in accordance with manufacturer’s instructions. Malfunctioning machines awaiting repair must be removed from service and labeled or tagged to prevent use. The facility should have a plan for the operation and routine maintenance of at least the following equipment and equipment systems:
- **V407** Interpretive Guidance states - Each patient, including his/her face, vascular access site, and bloodline connections, must be able to be seen by a staff member throughout the dialysis treatment. Allowing patients to cover access sites and line connections provides an opportunity for accidental needle dislodgement or a line disconnection to go undetected. This dislodgement or disconnection could result in exsanguination and death in minutes.
- **V412** states – Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d) (1) (i) of this section. V412 Interpretive Guidance states- Patients must have sufficient knowledge of emergency procedures to know how to handle emergencies, both in and out of the facility. Refer to V409 for the required areas of emergency education. V409 includes - What to do, where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for

instances when the dialysis facility is unable to receive phone calls due to an emergency situation and how to disconnect themselves from the dialysis machine if an emergency occurs.

- **V413** states - (3) Emergency equipment - Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.

Chapter 6: Patients' Rights



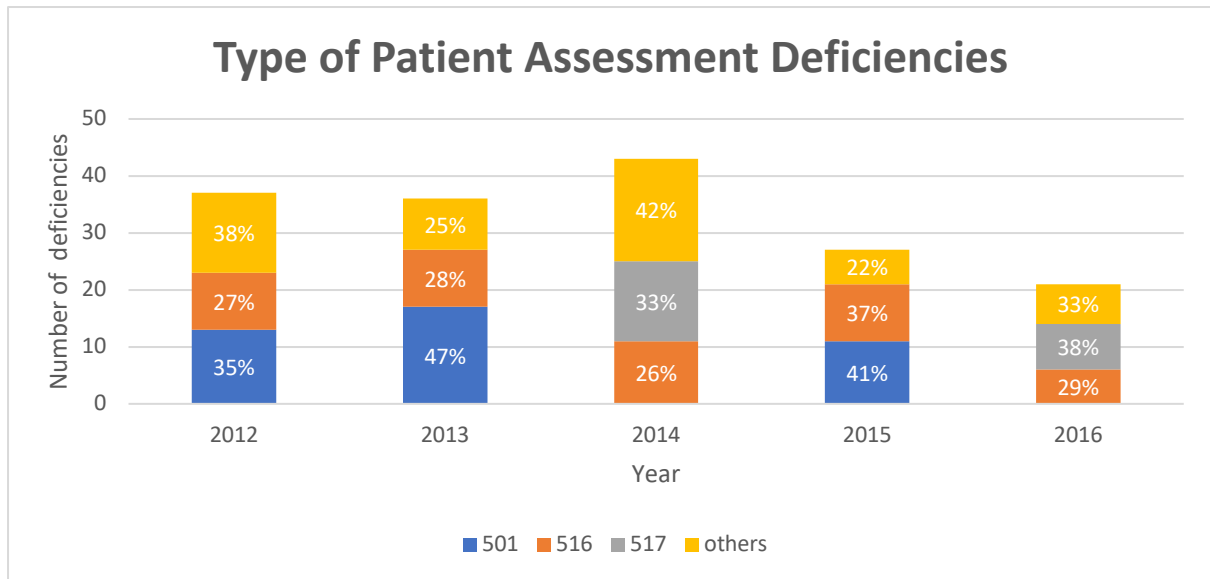
The bar chart above showed the type of patients' rights deficiencies between 2012 and 2016. V458 was the leading deficiency cited in 2012 and 2014. V465 is the single deficiency in this category in 2013. By and large, the patients' rights were rarely cited and much improved over the last two years of follow-up.

Chapter 6: Patients' Rights

Index Definition of Deficiencies:

- **V458** states ... (7) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis. The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients;
- **V465** Interpretive Guidance states - Each facility should develop and implement an internal grievance process, as is stated in the Condition for Governance at V765.

Chapter 7: Patient Assessment



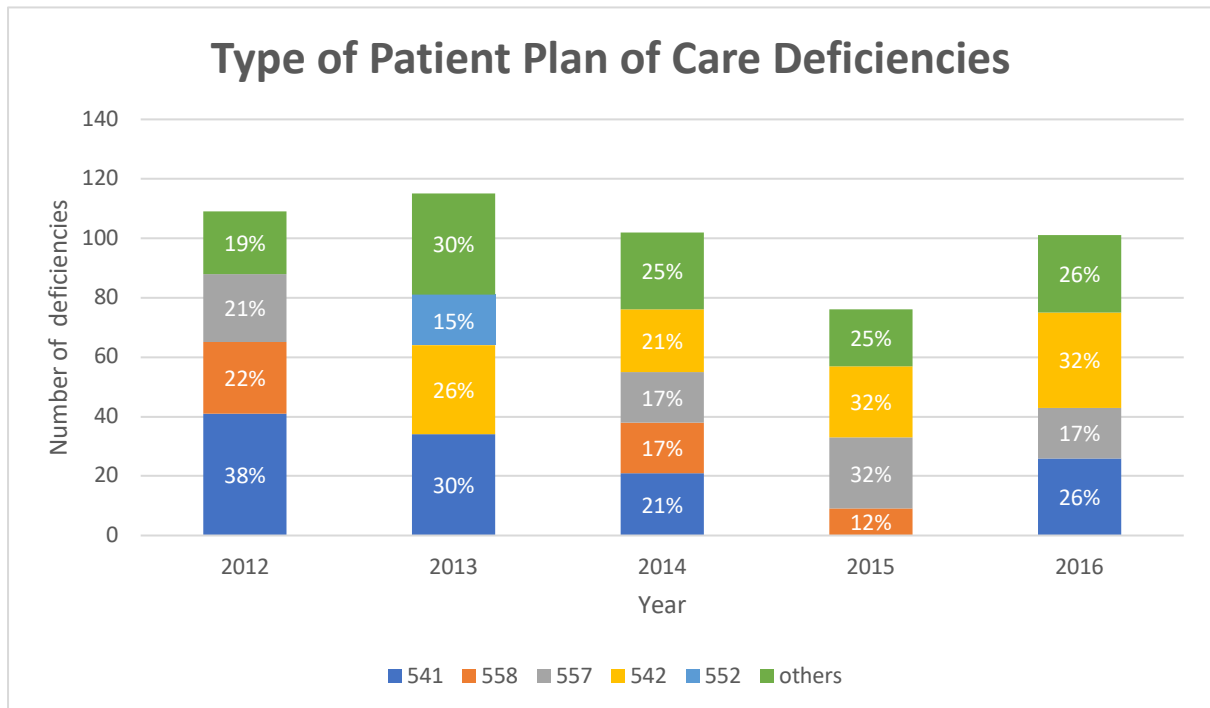
The bar chart above showed the top 2 and the other deficiencies in the patient assessment category between 2012 and 2016. By and large, the patient assessment deficiencies improved over the years of follow-up but with a similar deficiency pattern of patient assessment in these 5 years. V501 was the leading deficiency cited in this category in 2012, 2013 and 2015. V516 remained in the top 2 deficiencies cited between 2012 and 2016.

Chapter 7: Patient Assessment

Index Definition of Deficiencies:

- **V501** Interpretive Guidance states - The comprehensive patient assessment must demonstrate a congruent integration of the evaluations completed by each team member, identifying the patient's individual needs and allowing for planning for necessary care and services. Team members may choose to conduct one-on-one interviews with the patient or may opt to set up team meetings which would include the patient in order to collect the appropriate assessment information.
- **V516** states - (b) Standard: Frequency of assessment for patients admitted to the dialysis facility. (1) An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.
- **V517** states - (2) A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in § 494.90.

Chapter 8: Patient Plan of Care



The bar chart above showed the top 3 and the other deficiencies in the patient plan of care category between 2012 and 2016. By and large, patient plan of care category did not change significantly over the years of follow-up and maintained a similar deficiency pattern of patient plan of care in over the 5 years. V541 and V558 were quite high in 2012, but they showed a significant improvement in the following year. V557 and V542 did not show significant changes during the 5 years of data analyzed.

Chapter 8: Patient Plan of Care

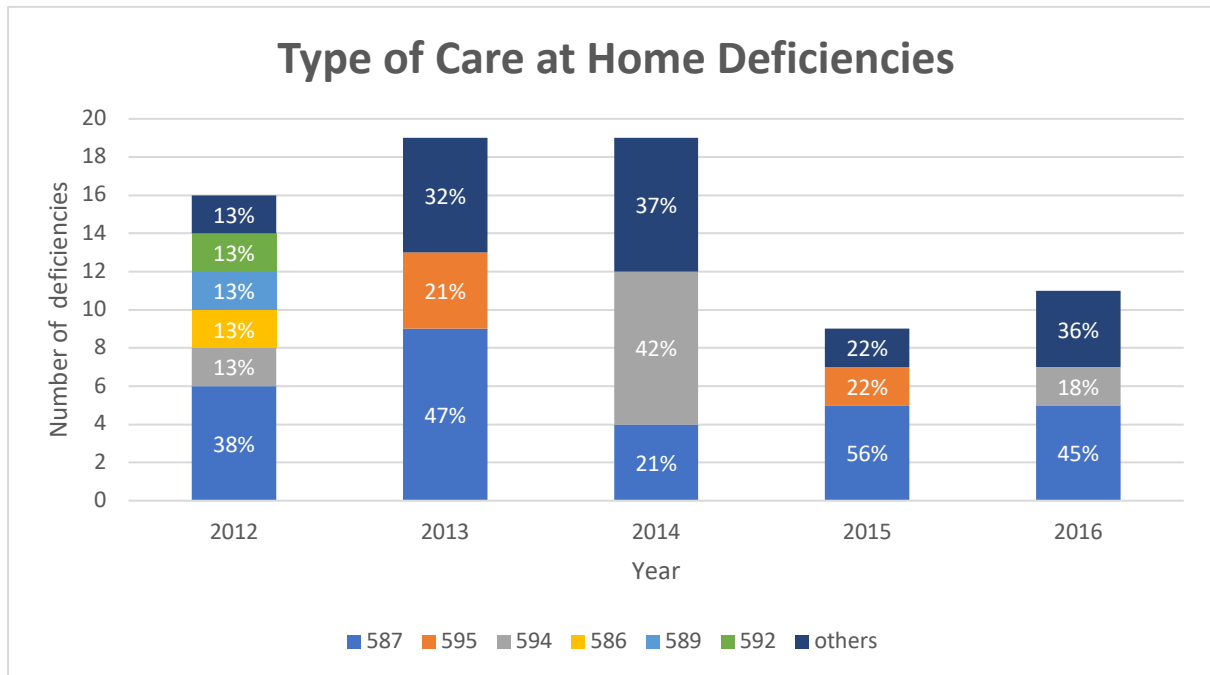
Index Definition of Deficiencies:

- **V541** states - The interdisciplinary team as defined at § 494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.
- **V542** Interpretive Guidance states - There must be an interdisciplinary plan of care developed for each patient. Facilities must have a system for developing patients' plans of care. The IDT members are expected to interact and share information from the comprehensive assessment to facilitate the development of the plan of care.
To ensure the development of a congruent, integrated patient plan of care, the facility may conduct IDT conferences or use another mechanism that ensures the development of an integrated plan. A substitute mechanism for a team conference needs to facilitate discussion among team members about the information gathered from the comprehensive patient assessment and provide the opportunity for team coordination and development of an effective, individualized plan of care for the patient to ensure the desired outcomes are achieved. To facilitate full team participation in conferences, any member, including the patient, may participate through telecommunication.
- **V552** Interpretive Guidance states - While this regulation allows the social worker to choose a "standardized mental and physical assessment tool," the tool selected by the National Quality Forum and the CMS CPMs for adult patients is the KDQOL-36 assessment survey. In the future, the percentage of patients taking this assessment survey annually will need to be reported electronically to CMS. Facilities may choose to use the KDQOL-36 from the implementation date of these regulations in order to have more comparable data once the KDQOL-36 is mandated. Pediatric patients should be assessed using an age appropriate assessment tool. "At regular intervals" means that the assessment survey is administered by the time of the first reassessment (i.e., within 4 months of initiating treatment), and repeated at least annually. Examples of an "as needed basis" would include repeat use of the survey with the patient who has a significant life changing event (e.g., loss of spouse, loss of job, recent move to a nursing

home) or a change in health status.

- **V557** states - (2) Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.
- **V558** states - Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in § 494.80(d).

Chapter 9: Care at Home



The bar chart above showed the top 2 and the other deficiencies in the care at home category between 2012 and 2016. By and large, the care at home improved over the years of follow-up. Except in 2014, V589 was the leading deficiency cited in this category between 2012 and 2016. On the other hand, V594 was very high in 2014, but showed a significant improvement in the following years.

Chapter 9: Care at Home

Index Definition of Deficiencies:

- **V586** Interpretive Guidance states - Medical records should include documentation of the training provided, and evidence that the patient/helper demonstrated competence in performing the home dialysis procedures.
- **V587** states - (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and
(3) Maintain this information in the patient's medical record.
- **V589** states- Services include, but are not limited to, the following:
(i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care.
- **V592** states (iv) Patient consultation with the members of the interdisciplinary team, as needed.

Interpretive Guidance states - ...The requirement at V560, which calls for at least monthly evaluation of all patients by a physician, an advanced practice registered nurse or physician assistant, applies to home dialysis patients, as well as in-center patients.

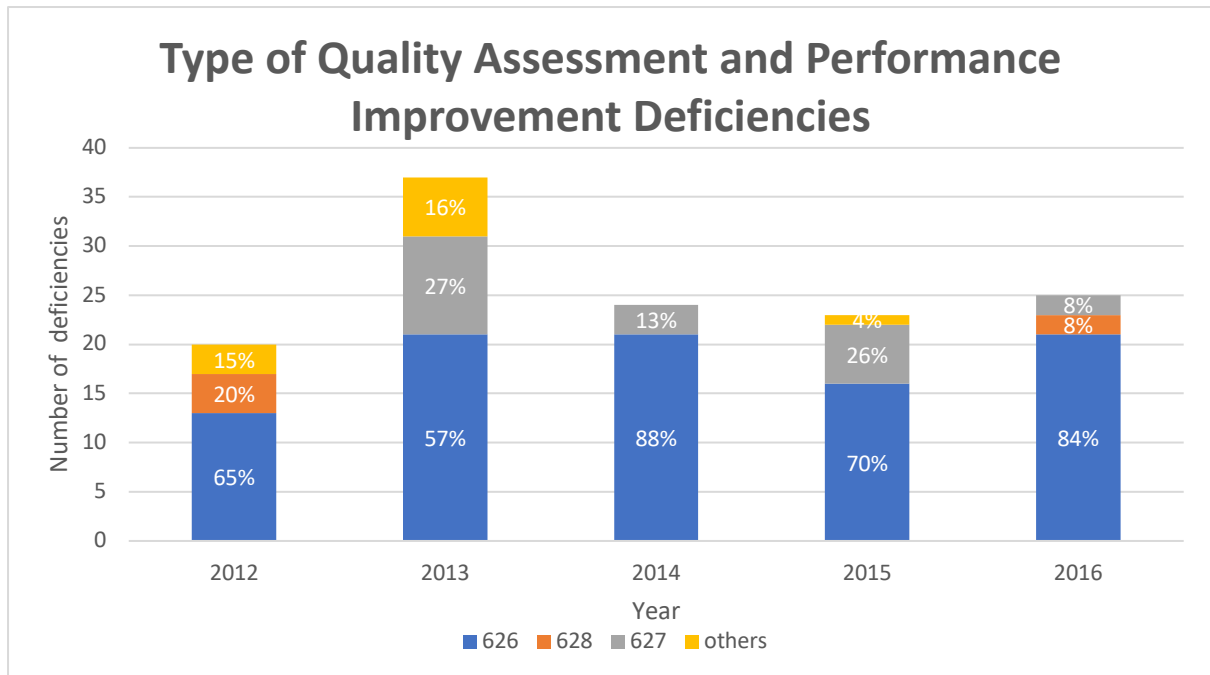
Interpretive Guidance states - The home dialysis patients must have access to members of the interdisciplinary team (i.e. registered nurse, dietitian, social worker, physician treating the patient, as defined at V501), who must be available to provide clinical services as needed by the patient. The interdisciplinary team must include the staff member who is responsible for the coordination of that patient's care. Contact may be in-person, by phone, by mail or by email with confirmation of patient receipt. The required minimum frequency of contacts may be defined by facility policy, but must meet the individual needs of each patient in accordance with their plan of care.

- **V594** Interpretive Guidance states - The home training and support facility is responsible for monitoring the quality of the water/dialysate used by home hemodialysis patients as required by the hemodialysis system manufacturer's recommendations and AAMI standards. Water treatment systems for home hemodialysis patients must produce water that meets the AAMI standards and the requirements specified in § 494.40(a) of these regulations. A chemical analysis of the product water must be done at the start of home treatment and at least once a year near the end of the usability of any disposable component, or when any modifications are made to the treatment components (other

than the replacement of disposable components), to ensure that AAMI-defined maximum allowable chemical contaminant levels are not exceeded. If chemical analysis is not conducted as described here, refer to V201 for RO systems or to V206 for DI systems. According to AAMI, more frequent than annual analysis may be needed if there are seasonal variations in source water quality or if the source water is supplied from a well, as detailed at V593. When any repairs are made to water treatment equipment, the impact on water quality should be evaluated and a chemical analysis performed if indicated. Note: the requirements for in-center use of preconfigured systems are detailed at V276.

- **V595** states - The facility must meet testing and other requirements of ANSI/AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.

Chapter 10: Quality Assessment and Performance Improvement



The bar chart above showed the top 2 and the other deficiencies in the quality assessment and performance improvement category between 2012 and 2016. By and large, the quality assessment and performance improvement did not change much over the years of follow-up and a similar deficiency pattern was observed in these 5 years. V626 remained the leading deficiency cited in this category between 2012 and 2016. Also, V627 remained in the top 2 deficiencies cited between 2013 and 2016.

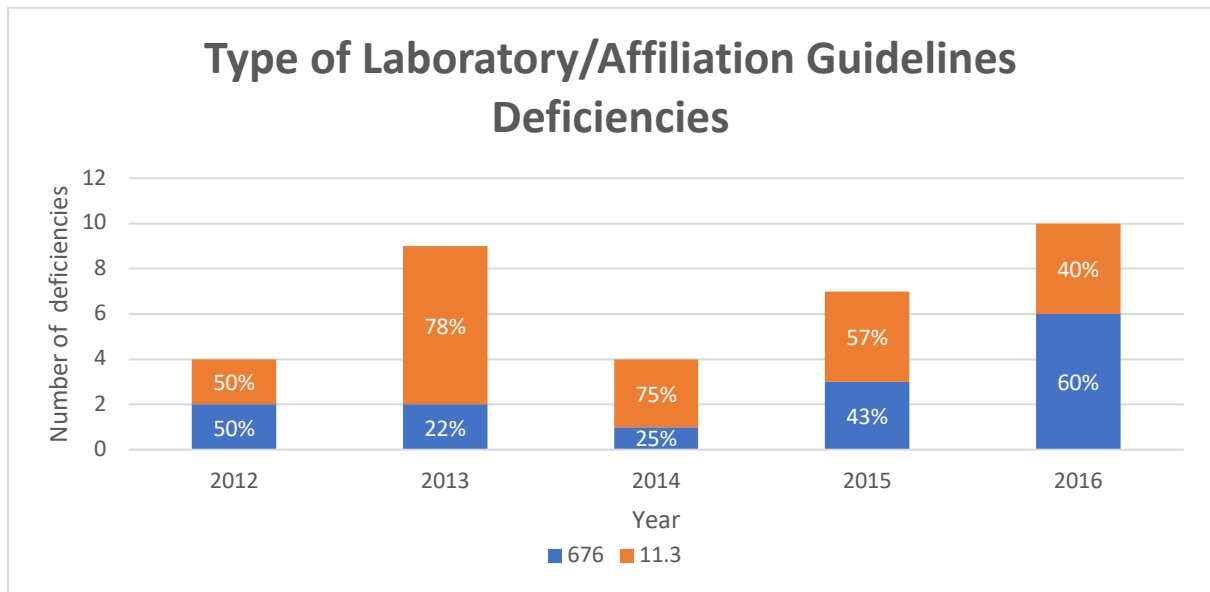
Chapter 10: Quality Assessment and Performance Improvement

Index Definition of Deficiencies:

- **V626** states - The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.
- **V627** Interpretive Guidance states - An "ongoing" program continuously looks at indicators as they are available, trends outcomes and develops an improvement plan when indicated. Generally this would require at least monthly review of indicators, since prescribed patient indicators are typically evaluated with laboratory results monthly and this serves as a functional time frame for trending of data within the facility. "Indicators" or "performance measures" include at least those specified in this Condition, as well as measures of water and dialysate quality and safety, and safe machine maintenance. Performance expectations are based on current professionally-accepted clinical practice standards. Refer to the Measures Assessment Tool (MAT) provided which lists these and the CMS Clinical Performance Measures (CPMs).
- **V628** Interpretive Guidance states- Data should be analyzed by the interdisciplinary team (IDT) on an ongoing basis. Based upon the data review, the IDT should discuss the areas which need improvement and develop, implement, and evaluate a plan for such improvement.
Interpretive Guidance states- Data should be analyzed by the interdisciplinary team (IDT) on an ongoing basis. Based upon the data review, the IDT should discuss the areas which need improvement and develop, implement, and evaluate a plan for such improvement. The facility must use broadly accepted, community-developed standards (e.g., CMS CPMs, NKF KDOQI, AAMI) as performance measures. Those standards which are expected to be measured and tracked are detailed on the Measures Assessment Tool (MAT). Where minimum outcome values have been determined, facilities are expected to provide care directed at achievement of at least the minimum outcome value by all patients. The IDT must work with individual patients who do not reach the target; this

work must be reflected in the patient's plan of care for that outcome. Refer to the applicable tag under the Condition for Plan of care for individual patient issues.

Chapter 11: Laboratory/Affiliation Guidelines



The bar chart above showed the type of laboratory/ affiliation guidelines deficiencies between 2012 and 2016. By and large, the total number of deficiencies increased over the years of follow-up with a similar pattern of laboratory/ affiliation guidelines deficiencies in these 5 years. 11.3* was the leading deficiency cited in this category between 2012 and 2015.

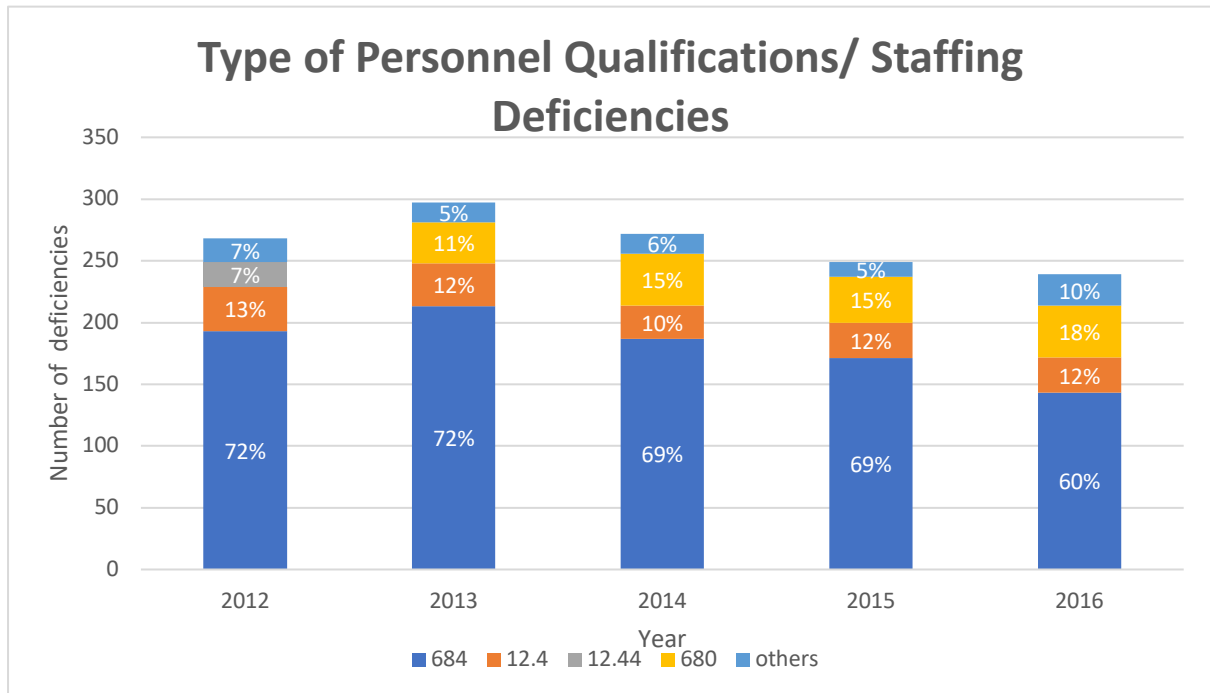
*11.3= COMAR 10.30.02.03

Chapter 11: Laboratory/Affiliation Guidelines

Index Definition of Deficiencies:

- **V676** states - The dialysis facility must provide or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.
- **COMAR 10.30.02.03 A** states - Location and Program Affiliation. (1) Freestanding dialysis facilities seeking a certification as a freestanding dialysis facility, under the terms of Health-General Article, Title 13, Subtitle 3, Annotated Code of Maryland, shall have, for the diagnosis and treatment of irreversible renal failure and its complications, arrangements with: (a) A laboratory that meets the needs of end-stage renal disease patients; (b) A hospital that can provide acute care services to meet the needs of end-stage renal disease patients; (c) A backup dialysis facility; and (d) Transplant services.

Chapter 12 : Personnel Qualifications / Staffing



The bar chart above showed the top 3 and the other deficiencies in the personnel qualifications/ staffing category between 2012 and 2016. By and large, the personnel qualification/ staffing improved over the years of follow-up with a similar deficiency pattern in these 5 years. V684 remained the leading deficiency cited in this category between 2012 and 2016. On the other hand, 12.4* and 12.44* remained in the top 4 deficiencies cited between 2013 and 2016.

*12.4= COMAR 10.30.02.04

*12.44= COMAR 10.030.04.04

Chapter 12 : Personnel Qualifications/ Staffing

Index Definition of Deficiencies:

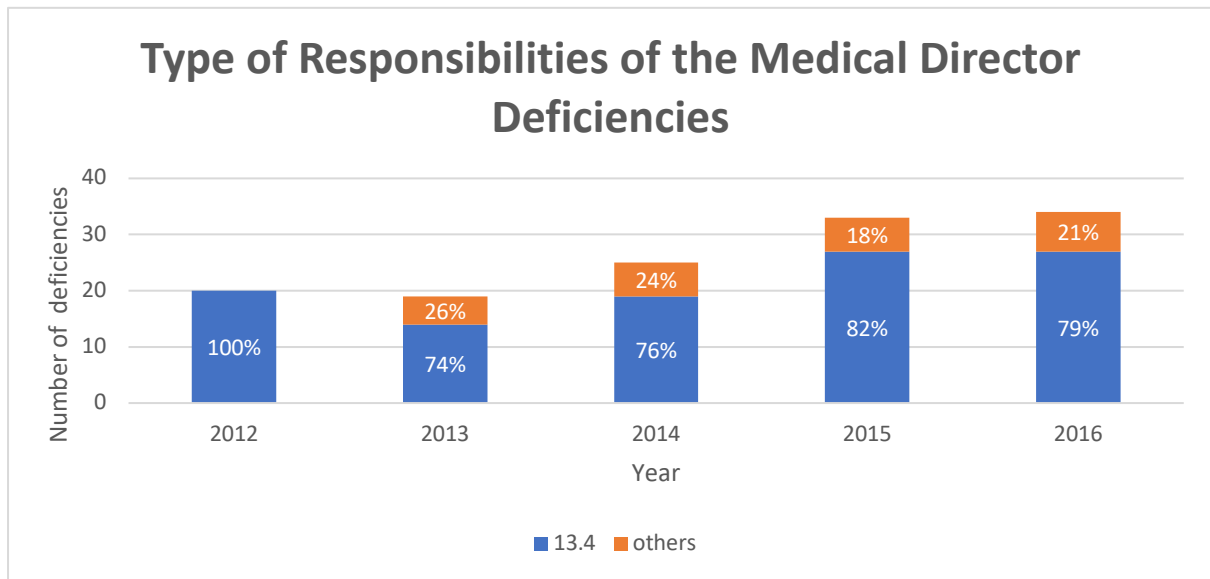
- **V 680** Interpretive Guidance states - This Condition defines the qualifications of dialysis facility staff and lists the minimum required content for patient care technician training programs. Compliance with this Condition is determined primarily by review of medical staff and personnel credential files, educational programs, policies and procedures for determining “competency” of the various staff members. Facilities must maintain current documentation to demonstrate personnel meet the basic requirements of their assigned roles, including any State specific requirements.
- **V684** states (b) Standard: Nursing services. (1) Nurse manager. The facility must have a nurse manager responsible for nursing services in the facility who must—(i) Be a full time employee of the facility;(ii) Be a registered nurse;
- **COMAR 10.30.02.04** (2) Charge Nurse. The charge nurse responsible for each shift: (a) Shall be a registered nurse; (b) Shall be on duty in the treatment area, at all times when patients are being treated, except for while on breaks, when the charge nurse shall be readily available; (c) Shall have at least 12 months experience in providing nursing care, including 6 months of experience in providing nursing care to patients on maintenance dialysis; and (d) May not be included in the staffing ratio except: (i) When there are nine or fewer patients; or ...

COMAR 10.30.02.04 D. Direct Patient Care Providers. (1) Staffing Ratio. (a) The monitoring individual-to-patient ratio at each facility shall be: (i) A minimum of one staff member to three participants; and (ii) Sufficient to meet the needs of patients. (b) The facility shall establish provisions for back-up staff coverage during unexpected illnesses, vacations, and holidays.

COMAR 10.30.02.04 H The social worker shall document progress notes: (a) At least quarterly for stable patients; and (b) At least monthly or more frequently for unstable patients including, but not limited to, patients experiencing:...

- **COMAR 10.030.04.04 E-** states -“The freestanding dialysis facility shall have adequate social services and dietetic staffing by licensed and trained professionals available to the dialysis patients”.

Chapter 13: Responsibilities of the Medical Director



The bar chart above showed the type of responsibilities of medical director deficiencies between 2012 and 2016. By and large, the total number of deficiencies increased over the years of follow-up with a similar pattern of responsibilities of the medical director deficiencies in these 5 years. 13.4* remained the leading deficiency cited in this category between 2012 and 2016.

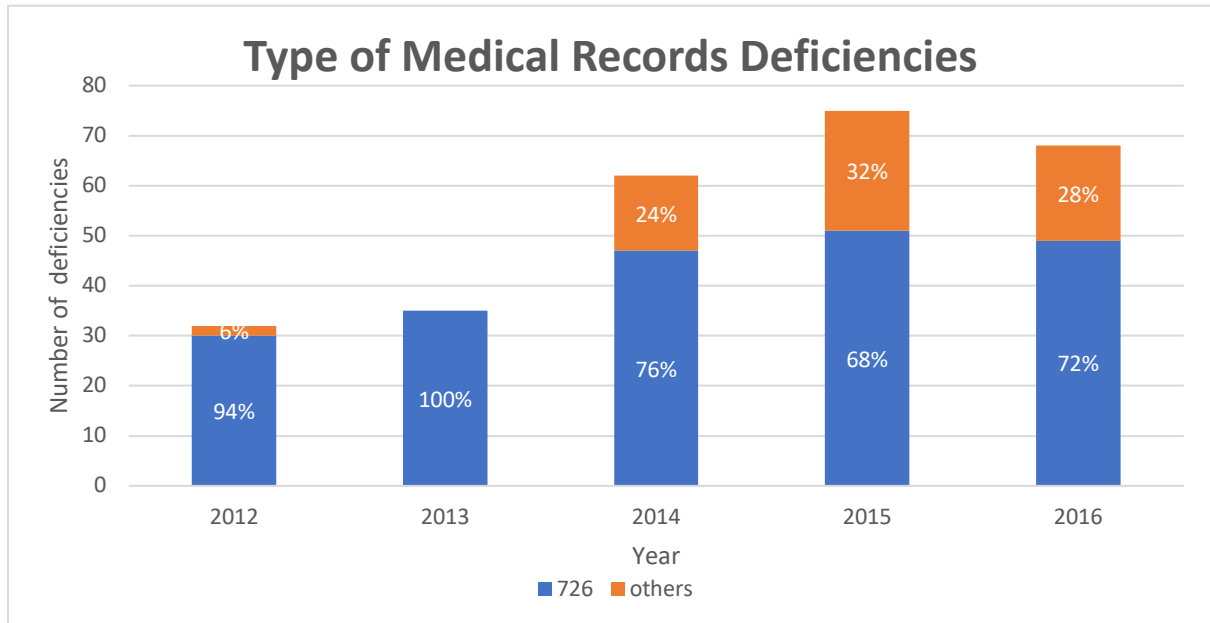
*13.4= COMAR 10.30.02.04

Chapter 13: Responsibilities of the Medical Director

Index Definition of Deficiencies:

- **COMAR 10. 30.02.04** states The Medical Director (u) “Assure attending physicians round on their patients at least monthly and document such on the patient’s progress notes;”

Chapter 14: Medical Records



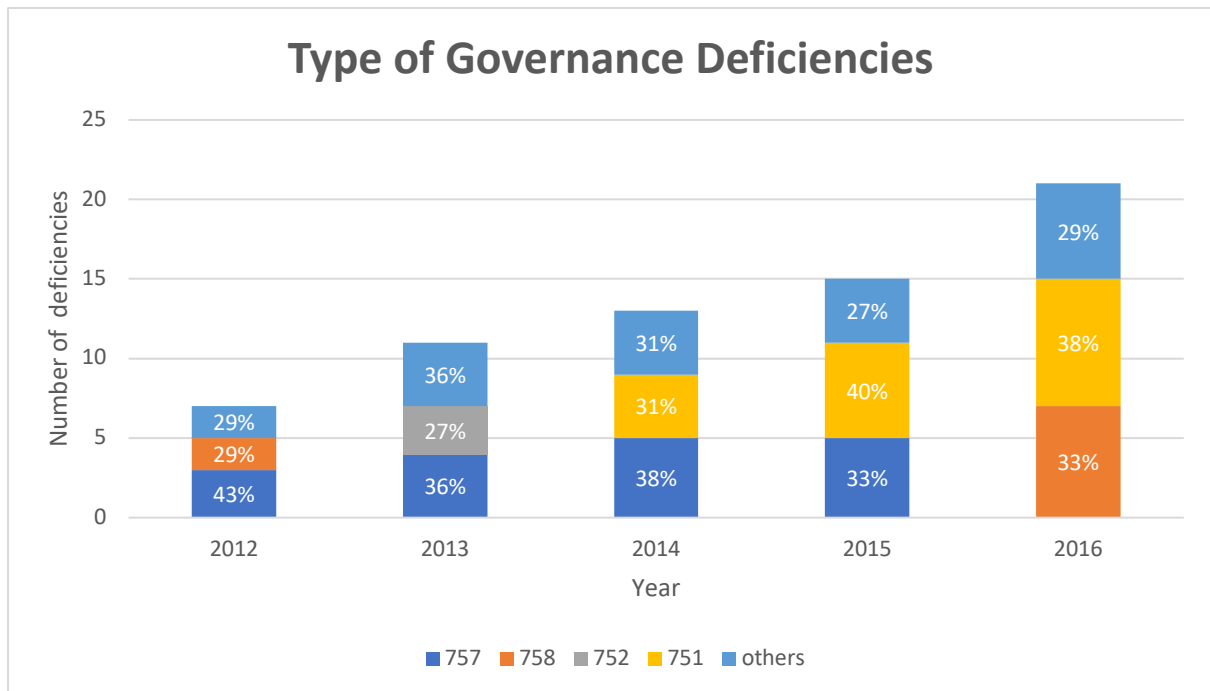
The bar chart above showed the type of medical records deficiencies between 2012 and 2016. By and large, the total number of deficiencies increased over the year of follow-up with a similar pattern of medical records deficiencies in these 5 years. V726 remained the leading deficiency cited in this category between 2012 and 2016.

Chapter 14: Medical Records

Index Definition of Deficiencies:

- **V 726** states - The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

Chapter 15: Governance



The bar chart above showed the top 2 and the other deficiencies in the governance category between 2012 and 2016. By and large, the governance deficiencies increased over the years of follow-up with a similar deficiency pattern in these 5 years. V757 was the leading deficiency cited in this category between 2012 and 2014, but it showed improvement in the subsequent 2 years. On the other hand, V751 showed an increase in the number of citations between 2014 and 2016.

Chapter 15: Governance

Index Definition of Deficiencies:

- **V751** - The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility.
- **V752** states - (a) Standard: Designating a chief executive officer or administrator. The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to—...
- **V757** states - (b) Standard: Adequate number of qualified and trained staff. The governing body or designated person responsible must ensure that—An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients;
- **V758** states - The registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs; Interpretive Guidance- The governing body is expected to make diligent efforts to promptly fill vacant positions. If the nurse manager, social worker, dietitian or other required or necessary position is vacant for more than a month, the governing body must make some provision for temporary coverage. If the facility “shares” the social worker or dietitian with multiple clinics or requires professional staff to perform non-clinical tasks, it must not negatively impact the time available to provide the clinical interventions required to achieve the goals identified in the patient's plan of care. The facility CEO or administrator is responsible to assure the professional support staff members have sufficient time available in the facility to meet the clinical needs of in-center and home dialysis patients.

Chapter 16: Conclusion

- In summary, we observe a decreasing trend in the deficiencies per facility between 2012 and 2016.
- Infection Control, Water and Dialysate Quality, Physical Environment, Patient Plan of Care and Personnel Qualifications/ Staffing are the top 5 categories of deficiencies.
- Laboratory/Affiliation Guidelines, Responsibilities of the Medical Director, Medical Records and Governance are the categories of deficiencies that increased over the years of follow-up; all the other categories of deficiencies either decrease or remain constant over time.
- Within each category of deficiencies, even though the number of deficiencies may vary from year to year, the type and the pattern of deficiencies are similar in these 5 years.