STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152668	A. BUILDING 00 B. WING	08/31/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
IRISH DIALYSIS	4350 S IRONWOOD DR SOUTH BEND, IN 46614

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V 0000 Bldg. 00	This was a Federal ESRD complaint investigation survey. Complaint #: IN00237127; Substantiated, Federal deficiencies related to the allegations are cited. Complaint #: IN00202620; Substantiated, Federal deficiencies related to the allegations are cited. Survey dates: 8/28/17 - 8/31/17 Facility # : 013676 Medicare Provider # : 152668 46 Incenter Hemodialysis Patients on census	V 0000		
V 0143 Bldg. 00	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and Based on observation, interview, and record review, the facility failed to ensure medications were labeled with the date	V 0143	V143	10/24/2017

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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	and time of opening and the initials of who had opened the medications for 1 of 1 facility. Findings 1. On 8/28/17 at 10:30 AM, multi - dose opened vials of heparin and Epogen were observed at the medication preparation station in the incenter hemodialysis room opened and not labeled with the time and date the medication had been opened or with the initials of who had opened the vials. 2. On 8/28/17 at 10:30 , Employee I, Registered Nurse, indicated the vials were not labeled with the date and time and initials of who had opened and used the vials. 3. The policy titled "Medication Policy" with a date of June 2017 stated, "If multi - dose vials are used to prepare saline flush syringes, they must be dated upon opening and discarded within 28 days unless the manufacturer specifies a different date for that vial."		Facility Administrator (FA) held mandatory in-service for all clinical Teammates (TMs) on 09/21/2017. In-service included review of Policy & Procedure 1-06-01 Medication Policy emphasizing Medications containing a preservative must be discarded 28 days after opening or accessed, unless the manufacturer specifies a different date. Each vial must be labeled with the initials of the person opening the vial and the expiration date. Verification of attendance at in-service evidenced by TMs signature on in-service sheet. FA or designee to conduct daily audits on all opened medication vials x 2 weeks, then weekly x 4 weeks, and then monthly to ensure compliance. FA will review results of audits with Medical Director during monthly Facility Health Meeting (FHM), minutes will reflect. FA is responsible for compliance with this plan of correction	
V 0452	494.70(a)(1) PR-RESPECT & DIGNITY			

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Bldg. 00	The patient has the right to- (1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD Based on record review, observation, and interview, the facility failed to) ensure patients had been treated with respect and dignity in 1 of 11 records reviewed (#10). The findings include: 1. Clinical record #10, admit date 5/14/17, failed to evidence the patient was treated with respect and dignity. The patient had signed the patient rights. This is evidenced by the following: A. During an observation on the incenter hemodialysis floor on 8/30/17 at 9:45 AM, Employee P, Patient Care Technician, was observed to care for patient #10. While assisting the patient, Employee P was observed to lean over quickly so the patient wouldn't touch her. Employee P stated as she leaned over quickly, "I don't want your cooties all over me. " B. During an interview on 8/30/17 at 12:30 PM, the medical director indicated that the staff were to be respectful to the patients. The medical director indicated not being aware of the meaning of the	V 0452	V452 FA held mandatory in-service for all clinical TMs on 09/21/2017. In-service included review of Policy & Procedure 3-01-07 Patient Rights and Patient's Standards of Conduct, Responsibilities, and Facility Rules emphasizing patients' have the right to be treated with respect, dignity and recognition of individuality, choices, strengths, abilities, cultural values, religious needs and personal needs to the extent possible during treatment. Every TM is responsible to promote an environment that ensures patients are treated with dignity and respect at all times. Verification of attendance at in-service evidenced by TMs signature on in-service sheet. FA or designee to conduct random observational audits to ensure TMs are promoting environment where patients are treated with dignity and respect daily x 2 weeks, weekly x 2 weeks and then monthly. FA will review results of audits with Medical Director during monthly FHM,	10/24/2017

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	word "Cooties." 2. The patient rights document titled "Patients Rights" with a origination date of 8/28/17 stated, "This form outlines the rights you have as a patient treating at a DaVita facility ... As a DaVita patient, I understand I am entitled to the following ... To be treated with respect, dignity." 3. The policy titled "Policy: 3:01 - 07 A Patient's Rights" stated, "Your rights as a patient: As a DaVita Patient I understand I am entitled to the following: To be fully informed of my rights [including privacy rights], responsibilities and all rules governing conduct related to patient care, services, and financial policies / responsibilities ... To be treated with respect, dignity and recognition of my individuality, choices, strengths, abilities, cultural values, religious needs and personal needs to the extent possible during treatment."		minutes will reflect. FA is responsible for compliance with this plan of correction Completion Date: 10/24/2017	
V 0543 Bldg. 00	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary			

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	team must provide the necessary care and services to manage the patient's volume status; Based on record review and interview, the facility failed to ensure in had provided the necessary care and services to manage the patient's blood pressure status in 2 of 11 incenter hemodialysis records reviewed (#3 and #12). The findings include: 1. A review of Clinical record #3 evidenced low blood pressures documented by Employee T, Patient Care Technician, during hemodialysis treatment on 7/31/17. The blood pressures were noted as 65 /49 and 75/53 at the end of the treatment at 3:29 PM and 3:30 PM. There was no documentation that the physician or Registered Nurse were notified. During an interview on 8/31/17 at 4 PM, the facility administrator and Employee G, Clinical Services Specialist, indicated the physician and nurse should have been notified due to the low blood pressure. 2. A review of Clinical record #12 evidenced high blood pressures dcoumented by Employee S, Registered Nurse, on a post treatment flow sheet	V 0543	V543 FA held mandatory in-service for all clinical TMs on 09/21/2017. In-service included review of Policy & Procedure #1-03-08 Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment emphasizing 1) TMs must verify patient dialysis prescription, and set all treatments as prescribed. Nurses are responsible for ensuring patients receive prescribed dose of dialysis and physician orders are followed; 2) Treatment monitoring must be completed at a minimum of every 30 minutes during, evaluation and documentation must include at a minimum patient's blood pressure, heart rate, blood and dialysate flows, arterial & venous pressures, fluid removal and/or replacement, vascular access status, line connections, patient status and subjective wellbeing. TMs must report and document any significant changes or indicators outside of ordered parameters to licensed nurse, licensed nurse must take appropriate action, contact physician if warranted, and follow physician orders. All findings, interventions and patient response will be documented in	10/24/2017

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	dated 7/21/17. The high blood pressure was documented through the treatment at 12:02 PM with a blood pressure of 185 / 100 and then at 2:32 PM with a blood pressure of 189 / 96 at the end of treatmnet. A blood pressure at 2:32 PM recorded by Employee S evidenced the post treamtn blood pressure was 194 / 96 with the patient seated and 193 / 102 for the patient standing. There was no documentation that the doctor was notified in the record. 3. The facility procedure titled "Hypotension" dated April 2017 stated, "If patient continuous to show signs and symptoms of hypotension notify physician and follow physician orders."		patient's medical record. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. FA or designee to conduct daily audits on 25% of patient treatment flow sheets x 2 weeks, then weekly x 4 weeks, and then monthly on 10% of treatment sheets to ensure compliance. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FA is responsible for compliance with this plan of correction Completion Date: 10/24/2017	
V 0544 Bldg. 00	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. Based on record review and interview, the facility failed to ensure the prescribed	V 0544	V544	10/24/2017

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	dialysate was used in 2 of 11 incenter hemodialysis records reviewed (#1, #5), failed to ensure the treatment time followed the prescription order for 2 of 11 records reviewed (#8 and #11), and failed to ensure the blood flow rate was followed for the prescription order for 2 of 11 records reviewed (#1 and #4). The findings include: Regarding a physician order change for a dialysate change 1. A review of the adverse occurrence report log document dated July 2017 evidenced a facility issue on 7/21/17. This was reported as an environmental / technical problem that occurred before / during / after treatment. This adverse event document stated, "FA [facility administrator] aware of issue as it occurred. Contacted MD [medical director] and nephrologists to make aware immediately. CSS [clinical services specialist] ... also contacted on 7/21/17 as it happened. No patient issues. Nephrologists gave ... orders for different bath orders. Comments: The 2 K bath had airlocked and unable to distribute acid to loop because of high conductivity outside of policy range. All physicians ordered new baths or patient		FA held mandatory in-service for all clinical TMs on 09/21/2017. In-service included review of Policy & Procedure #3-02-03 Physician Orders for Patient Care emphasizing all written/verbal/telephone orders must be transcribed upon receipt into the patient's medical record and must include all of the following: Date and time order was given; New order or change in existing order; Name and credentials of physician giving order; Name and credentials of licensed teammate receiving the order. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. FA held mandatory in-service for all clinical TMs on 9/21/2017. In-service included review of Policy & Procedure #1-03-08 Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment emphasizing 1) TMs must verify patient dialysis prescription, and set all treatments as prescribed. Nurses are responsible for ensuring patients receive prescribed dose of dialysis and physician orders are followed; 2) In the event that the patient's dialysis prescription is not being met the reason must be documented and licensed nurse informed. Nurses are responsible	

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	dialysis discontinued." 2. A review of a document titled "Snappy [Reconcile plan vs. actual"] dated 7/21/17 and retrieved on 8/29/17 evidenced the names of patients from the 7/21/17 adverse event. The patient names included patients #1, #3, #5, and #7. These documents were written by the facility administrator to show which patients lacked physician notes. Included in the lack of physician notes were patients #5. None of these patients listed had physician orders for the adverse event that occurred on 7/21/17. 3. Clinical record #1 evidenced a physician order dated 4/26/17 with incenter hemodialysis orders including incenter hemodialysis treatment 3 times a week and the dialysate prescription: Potassium 2.00 mEq / L [milli equivalents / liter], Calcium 2.5 mEq / l, and Bicarb 35 mEq / l. There were no orders for a change to a different bath on 7/21/17. The patient's post treatment flow sheet dated 7/21/17 evidenced the patient had incenter hemodialysis treatment on 7/21/17 from 11:59 AM - 4 PM. There was no documentation of the adverse event and the change over to the Potassium 3.0 mEq / L dialysate bath that		for taking appropriate action, assess patient, contacting physician if warranted and follow physician orders, orders received must be documented in the patient's medical record. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet. FA or designee to conduct daily audits on 25% of patient treatment flow sheets x 2 weeks, then weekly x 4 weeks, and then monthly on 10% of treatment sheets to ensure compliance. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FA is responsible for compliance with this plan of correction Completion Date: 10/24/2017	

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	occurred during the treatment. There was no notice of any new orders on this document. The patient was able to complete treatment. 4. A review of Clinical record #5 evidenced a physician order dated 6/14/17 with incenter hemodialysis orders: incenter hemodialysis treatment 3 times a week and the dialysate prescription: Potassium 2.00 mEq / L, Calcium 2.5 mEq / l, and Bicarb 35 mEq / l. There were no orders for a change to a different bath on 7/21/17. A. The patient's post treatment flow sheet dated 7/21/17 evidenced the patient had incenter hemodialysis treatment on 7/21/17 from 11:45 AM - 3:02 PM. There was no documentation of the adverse event and the change over to the Potassium 3.0 mEq / L dialysate bath that occurred during the treatment. There was no notice of any new orders on this document. The patient was able to complete treatment. B. During an interview on 8/31/17 at 4:35 PM, the administrator and Employee G, Clinical Services Specialist, indicated this patient had been effected by the adverse event and the patient's had been changed from 2 K to 3 K without documentation of this change or the			

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	writing of the physician orders for this change. 6. During an interview on 8/29/17 at 2:15 PM, the facility administrator indicated that no patients had orders written for the switch from 2 K to 3 K baths due to the airlock problem that occurred (See the document below that showed the lack of orders and physician notes.] 7. During an interview on 8/29/17 at 4:45 PM, Employee G, Clinical Services Specialist, indicated that after the air lock occurred in the 2 K bath line that the machines alarmed with conductivity issues. 8. During an interview on 8/29/17 at 2 PM, the facility administrator indicated the adverse event had occurred with the air lock concern with the 2 K bath. The physicians were notified. No physician orders were written for these phone calls. 9. During an interview on 8/29/17 at 4:45 PM, Employee G, Clinical Services Specialist, indicated that after the air lock occurred in the 2 K bath line that the machines alarmed with conductivity issues. Regarding the prescribed treatment time			

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	not followed 10. Clinical record #8 failed to evidence the prescribed treatment time of 225 minutes followed at a treatment on 7/24/17. A post treatment flowsheet dated 7/24/17 with a treatment initiation at 6:27 AM and discontinuation at 10:39 AM evidenced the patient's treatment was 253 minutes instead of the prescribed 225 minutes. There was no explanation about why this occurred or notice to the physician. 11. Clinical record #11 failed to evidence the prescribed treatment time of 300 minutes was followed at a treatment on 7/21/17. A post treatment flowsheet dated 7/21/17 with a treatment initiation at 7:03 AM and discontinuation at 10:30 AM evidenced the patient's treatment was 211 minutes instead of 300 minutes. There was no explanation about why this occurred or notice to the physician. 12. A review of clinical record #12 failed to evidence the prescribed treatment time of 240 minutes was achieved during the treatment.			

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	A post treatment flow sheet dated 7/21/17 with a treatment initiation at 11:35 AM and discontinuation at 2:32 PM evidenced the patient dialyzed 177 minutes instead of 240 minutes. The nurse documented, "Patient refused to run entire treatment." There was no documentation the physician was contacted due to the treatment not being completed. Regarding the blood flow rate on the prescription was followed for 1 of 10 incenter hemodialysis records 12. Clinical record #1 included hemodialysis orders that identified the blood flow rate (BFR) was to be 400 milliliters per minute. A. The flow sheet dated 8/16/17 evidenced BFRs of 300, 350 during the treatment with no explanation as to why the BFR was not followed. B. During an interview on 8/31/17 at 4 PM, Employee G, Clinical Services Specialist, indicated the blood flow rate was not as ordered. 13. Clinical record #4 included hemodialysis orders that identified the BFR was to be 500 milliliters per minute.			

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	A. The flow sheet dated 8/9/17 evidenced BFRs of 400 during the treatment with no explanation as to why the BFR was not followed. 14. The undated agency policy titled "Policy: 3-02-03 Davita Inc." stated "Title: Orders for Patient Care Purpose: To verify that orders are properly documented, transcribed, verified and implemented in a timely manner for patient care in DaVita facilities and meet all DaVita, federal and applicable state regulations ... Policy: 1. A physician, in accordance with DaVita Medical Staff Bylaws, federal and state regulations, provides orders for patient care activities in one of the following ways: a. Hand writes or electronically enters orders in the patient medical record b. Gives verbal or telephone orders c. Gives orders via DaVita approved secure message via DaVita approved secure message service ('Secure Message'). Note: Contact Team Matrix for list of approved secure messaging services d. Approves by signature patient specific standing orders. 2. All verbal/telephone orders will be "read back" to the physician giving the verbal/telephone order to verify that the order was received correctly. 3. All verbal/telephone orders will be transcribed upon receipt into the patient's			

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	medical record and will include all of the following: a. Date and time order was given b. New order or change in existing order c. Name and credentials of physician giving order d. Name and credentials of licensed teammate receiving the order ...7. Registered Nurses accept verbal/telephone orders in accordance with state regulations. Registered Nurses and certified physician extenders (per DaVita policy) may write orders for medication/treatment changes based on patient-specific protocols that have been signed by the attending physician and approved by the facility Medical Director and Governing Body ..."			

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V 0634 Bldg. 00	494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification. Based on record review and interview, the facility failed to ensure its adverse occurrence report log identified an adverse event reviewed in a review of 2 of 11 clinical records reviewed (#6 and #9). The findings include: 1. A review of clinical record #6 evidenced the patient's dialyzer clotted and the machine was reset up so that treatment could continue during treatment on 7/21/17. The patient's clotted lines were reset up at 8:27 PM. This event was not listed on the adverse occurrence log for July 2017. 2. A review of the adverse occurrence log for July 2017 failed to show a report of an event on 7/21/17. 3. During an interview on 8/29/17 at 2:20 PM, the facility administrator indicated that the event was not reported	V 0634	V634 FA held mandatory in-service for all clinical TMs on 9/21/2017. In-service included review of Policy & Procedure 13-01-02 Adverse Occurrence Reporting Policy (Non-Teammate Related) emphasizing 1) an Adverse Occurrence Report (AOR) is any unexpected event that is inconsistent with the routine operation of a dialysis facility, routine provision of acute dialysis or ancillary renal-related services may be an adverse occurrence. Such adverse occurrences include, but are not limited to, personal injury or potential personal injury to a patient. 2) All adverse occurrences must be promptly reported to the Facility Administrator/Manager or designee. The teammate involved in the adverse occurrence or who witnessed the adverse occurrence firsthand will complete an AOR. The teammate must complete the AOR as soon after the occurrence as is	10/24/2017

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152668	A. BUILDING 00 B. WING	08/31/2017

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	on the adverse occurrence report log for July 2017. 4. A review of clinical record #9 evidenced the patient only dialyzed for 3 minutes and infiltrated at 5:42 AM on 8/30/17. 5. During a review on 8/31/17 at 5 PM, there was no evidence that an adverse event report had been completed or any no in the electronic medical record had been completed. 6. During an interview on 8/31/17 at 5 PM, the facility administrator indicated the adverse occurrence documentation should be completed by the end of the day of the occurrence. The doctor had been notified. 7. A review of a policy titled "Adverse Occurrence Reporting Policy" dated June 2016 and reviewed September 2015 stated, "An unexpected event that is inconsistent with the routine operation of a dialysis facility, routine provision of acute dialysis ... all adverse occurrences will be promptly reported to the facility administrator / manager or designee ... 4. An AOR [adverse event report] must be completed by accessing the link in the Snappy or through Davita intranet. The AOR is to be completed with as much		reasonably possible, but no later than the completion of the teammates' shift during which the adverse occurrence happened. 3) The AOR is to be completed with as much factual detail as is known, including the full name of the facility, the facility number, the date and time of the occurrence, the name of the injured party or patient involved, as applicable. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet FA or designee to conduct weekly audits on 25% of patient treatment flow sheets x 2 weeks, then weekly x 4 weeks, and then monthly on 10% of treatment sheets to verify completion of an AOR if identified to ensure compliance. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FA is responsible for compliance with this plan of correction Completion Date: 10/24/2017	

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	factual detail as is known ... examples of reportable occurrences ... clotted dialyzer."			
V 0727 Bldg. 00	494.170(a) MR-PROTECT PT RECORDS FM LOSS/CONFIDENTIAL The dialysis facility must- (1)Safeguard patient records against loss, destruction, or unauthorized use; and (2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following: (i) The transfer of the patient to another facility. (ii) Certain exceptions provided for in the law. (iii) Provisions allowed under third party payment contracts. (iv) Approval by the patient. (v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.			
	Based on observation, record review, and interview, the facility failed to ensure the confidentiality and privacy of 1 of 1 clinical record document observed on the treatment floor discarded by Employee D, Registered Nurse. The findings include: 1. During a observation on the treatment floor on 8/30/17 at 10:30 AM, Employee	V 0727	V727 FA held mandatory in-service for all clinical TMs on 09/21/2017. In-service will include review of Policy & Procedure 3-01-07 Patient Rights and Patient's Standards of Conduct, Responsibilities, and Facility Rules emphasizing 1) Patients are entitled to know their medical	10/24/2017

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	D, Registered Nurse, was observed to discard the treatment orders for patient #8 into the biohazard waste container near station #13. These orders had been in station #13 on machine #8252303. Employee D discarded this document while cleaning the station. A. During an interview on 8/30/17 at 11 AM, the facility administrator indicated the confidential document did not belong in the biohazard container but should have been shredded. B. A document titled "Pretreatment" with a current treatment date of 8/30/17 was identified as the document like the one discarded into the biohazard container by the facility administrator. C. A review of the patient's rights dated 2/1/16 evidenced the patient had received and signed for the patient rights on this dated. 2. The agency document titled "Patient Rights" dated 2/1/16 stated, "As a Davita patient you are entitled to the following ... to know your medical records and the information contained will be considered private and confidential."		records and the information contained will be considered private and confidential; 2) Iron Mountain is the appropriate receptacle to place patient flowsheet records when no longer needed for the dialysis treatment. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet FA or designee to conduct random observational audits to ensure TMs are discarding patient flowsheets appropriately daily x 2 weeks, weekly x 2 weeks and then monthly. FA ordered one iron mountain receptacle for the treatment area for convenience of use. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FA is responsible for compliance with this plan of correction Completion Date: 10/24/2017	