



New York State Electronic Certificate of Need (NYSECON) Clinical Checklist Documents Submission Guidance

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Please Note: After the materials requested on this NYSECON Clinical Checklist are reviewed offsite, the onsite pre-opening survey will be conducted. All necessary equipment and supplies must be present at that time of the onsite survey, and the facility must be patient ready.

For new providers and providers changing ownership, Administrators **MUST** create a **Health Commerce System (HCS)** account specific to the health care facility. For guidance on how to acquire an HCS account for your facility, click the following link:

https://www.health.ny.gov/prevention/immunization/information_system/providers/hpn_account_instructions.htm

For NYS Regulations pertaining to free-standing Diagnostic and Treatment Centers (Clinics), refer to State Hospital Code:

Article 6: Diagnostic and Treatment Centers: NYCRR Title 10: Part 750, Part 751 (751.1 to 751.11), Subpart 752-1 (752-1.1 to 752-1.5) available on our website at <https://www.health.ny.gov/facilities/hospital/>

Note: All policies and procedures in the Center Manual must be co-signed by the Medical Director and dated. The Center’s Policies and Procedures must be reviewed at least annually and revised as necessary.

#	Name of Documentation	Minimum Requirements	Guidance
1	Organizational Chart (delineating authority, to include but is not limited to):	<ul style="list-style-type: none"> a) Administrator b) Medical Director c) Director of Nursing d) Define who has authority over the Consultants (e.g. Pharmacy, Medical Record, Social Worker - if applicable) 	
2	Governing Authority Bylaws	<p>Operator -</p> <ul style="list-style-type: none"> a) Rules and Bylaws including selection of members, number of members needed for quorum; at least quarterly meetings (except if sole proprietor), committees (except if sole proprietor), and appointment of Department Directors must be developed. <ul style="list-style-type: none"> o Responsibilities of the governing body including involvement in Quality Assurance and Performance Improvement (QAPI) o Meeting schedule b) Scope of Services and Purpose of the Center 	
3	Medical Provider Bylaws and Rules	<ul style="list-style-type: none"> a) Bylaws, Rules and Regulations of the Medical Staff - These Medical Bylaws are to be approved by the Operator. If Physician Assistants or Registered Specialist Assistants are being used, the Medical Bylaws are to include the provision of formal procedures for the evaluation of the application and credentials and 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> recrediting of Physician Assistants and Registered Specialist Assistants applying for privileges to provide medical services under a Physician's supervision. b) History & Physical Policy c) Physician Evaluation, Admission Assessment and Discharge Policies <ul style="list-style-type: none"> o Development of a comprehensive care plan 	
4	Content of Medical Provider Credential and Quality Assurance File	MDs and Mid-Levels - <ul style="list-style-type: none"> a) License b) Board Certification c) Delineation of privileges supported by recommendations d) Appointment Letter with Recredentialing Bi-Annually e) DEA (Drug Enforcement Administration) f) BCLS (Basic Cardiac Life Support) or ACLS/PALS (Advanced Cardiac Life Support / Pediatric Advanced Life Support) as per Emergency Protocol. g) Applications for admission to staff containing Statement of Training and Experience h) Evidence of ongoing Quality Review i) Evaluation of application & credentials of Mid-level Practitioners. j) Policy regarding oversight of Non-Physician Mid-Level Providers k) Evidence of Admitting Privileges at a Medicare-participating hospital or local non-participating hospital that provides Emergency Services l) Receipt of Bylaws 	Actual Credential Files for staff will be reviewed onsite. Submit a sample file - TEMPLATE Only.
5	Content of all Staff Personnel and Health File	<ul style="list-style-type: none"> a) All applicable staff <ul style="list-style-type: none"> i) License ii) BCLS or ACLS/PALS as per emergency protocol iii) Orientation Skills Checklist - specific to job description and title (i.e. Nursing, Surgical Technologists, etc.) b) Health Files <ul style="list-style-type: none"> i) Measles and Rubella Titers or proof of immunizations ii) Mantoux annually or chest X-ray (CXR) on file iii) Pre-Employment and Annual Health Exam iv) Rubeola (Post 1956) v) Influenza vi) Hepatitis B vii) Vaccine or declined 	(Include MDs, RNs, Clerks, Mid-Level Practitioners, Techs, Nursing Assistants, etc.)
6	Staff Education and Training	<ul style="list-style-type: none"> a) Job Description for all staff with position requirements b) Evidence that the facility provided copies of policies regarding employment c) Evidence that the facility provided orientation to staff on facility's policies d) Patient care responsibilities 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> e) In services for DOH mandated courses on HIV Confidentiality and HIPAA/ Patient Rights/ Advance Directives/ Infection Control and Universal Precautions/ Fire Safety/ Child Abuse- Domestic Violence and Human Trafficking f) Advance Directives Policy g) Annual performance evaluations and competency assessments 	
7	Staffing Plan	<ul style="list-style-type: none"> a) Staffing Plan for each type of staff (MDs, Nurses, Techs, other) with list of names and staff titles b) Basic Staffing Pattern including supervision c) Hours of Operation 	
8	Quality Assurance Plan	<ul style="list-style-type: none"> a) The Operator who will develop and implement a written Quality Assurance (QA) Program. b) The QA Plan and oversight of technical operations and quality audits. c) The QA plan will identify the Medical Director who is responsible for the supervision of the QA Program and for reporting the activities of the Program to the Operator. QA Audit Plan which will specifically include the number of charts that will be reviewed and will define the timeframe in which the reviews will occur. The plan will include the indicators/review criteria that will be used. d) Please specify: the responsibilities of participants; regularly scheduled reviews of Medical Records, Complaints and Incidents; participation by each professional service; findings and actions to be taken to resolve identified problems, and timely implementation of corrective actions with periodic assessments of the results of such actions and how information gets to the Governing Body. e) Incident/Occurrence Reporting Policy and Incident types will include reporting timeframes. 	
9	Infection Control Plan	<ul style="list-style-type: none"> a) Name of the Infection Control Practitioner. b) Infection control committee c) Demonstrate how IC Guidelines are being used to follow national recognized IC Standards (CDC, AORN, APIC, SHEA). d) System used to actively identify infections related to procedures performed and documentation of tracking. e) How IC is incorporated into QAPI? f) Policies and Procedures (Based on National Standards) for: <ul style="list-style-type: none"> o Hand hygiene o Specific measures for MDROs (Multiple Drug Resistant Organisms) o Injection practices o Policy for cleaning glucometers 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> ○ Multi-dose medications ○ Policy for reportable communicable diseases ○ Orientation of all new employees in IC and personal hygiene; with ongoing education in IC ○ Screening and surveillance of patients and HCWs (Health Care Workers) for risk of/actual infections and communicable diseases ○ Methods to minimize source & transmission of infection ○ Active surveillance program ○ Provision for infected or contaminated patients ○ Isolation Procedures ○ Hazardous Waste Handling ○ Sterilization/autoclave spore-testing/validation single use devices (for reprocessed check FDA requirements) ○ Single use equipment ○ Offsite Sterilization Contract ○ Sterilizing equipment testing results ○ Separation of clean equipment/instrument storage ○ Patient follow up after discharge, tracking, documented in Medical Record ○ Resuscitative techniques (codes) ○ Special provision for infected or contaminated patients ○ Needle stick injuries/potential HIV exposure ○ Blood Spills 	
10	Patient Emergency Plan	<p>Patient Emergency Policy specification of who (MD, Mid-Levels, RN, etc.) requires BCLS (basic life support)/ACLS (advanced life support)/PALS (pediatric advanced life support); (a practitioner qualified in resuscitation technique and emergency care must remain present until all patients are discharged).</p> <ul style="list-style-type: none"> a) Emergency protocol if patient codes (process; requirements of staff) b) Emergency equipment and supplies; contents of crash cart. (Emergency drugs and supplies as per Medical Staff {formulary by Anesthesia}) c) Emergency call system d) Generator testing if facility has a generator e) Evacuation plan (fire) f) Disaster Preparedness Plan (coordination of plan with State and Local authorities as appropriate) g) All Code Policies h) Preventative maintenance on equipment i) Operation, security and maintenance of the facility 	

#	Name of Documentation	Minimum Requirements	Guidance
11	Operational and Clinical Policies and Procedures	<p>a) Nursing:</p> <ul style="list-style-type: none"> i) Frequency of nursing monitoring and prior to discharge ii) Medication administration iii) Medication errors iv) Adverse reactions <p>b) Patient Rights Policies and Procedures:</p> <ul style="list-style-type: none"> i) Signage (All Waiting Rooms require signage) ii) Policy for distribution of Patient Rights and Advance Directives given with evidence documented in the Medical Record iii) Document in the Medical Record if the patient has a Health Care Proxy or not. iv) Grievance/Complaint Policy that includes that the facility investigates, providing a written response within thirty (30) days of findings of investigation (if requested by patient), and notifying patient that if they are not satisfied, they may complain to DOH, OPHSM v) Abuse and Neglect Policy vi) Exercise rights on behalf of a patient judged legally incompetent vii) Policy that addresses delegation by a patient to a representative viii) Communicating with patient with communication barrier ix) Child abuse reporting. x) Domestic Violence – Identification and treatment of victims xi) Surprise Bill Law xii) HIV Confidentiality xiii) HIPAA/Confidentiality xiv) Provision of service (details of nondiscrimination) xv) Informed Consent xvi) Human Trafficking xvii) Patients are provided with information to inform them of the various treatment modalities. <p>See Link below for Required Patient Rights publications https://www.health.ny.gov/professionals/patients/patient_rights/</p> <p>c) An Advance Directive Policy that Addresses the Following:</p> <ul style="list-style-type: none"> i) Provision of information to patients on Advance Directives <ul style="list-style-type: none"> o Policy for honoring or not, the patient’s Advanced Directives for DNR (Do Not Resuscitate), if one is in the patient’s medical record. o Ensure if the patient is transferred to the hospital that a copy of the Advanced Directive is provided with the copy of the medical record when the patient is transferred. 	

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		<p>d) Social Work Services:</p> <ul style="list-style-type: none"> i) Policy for evaluation of patients for medically related personnel and social problems ii) Staff member/position designated to coordinate with community services. iii) Referral to health-care facility or practitioner for service(s) not available at the facility. <p>e) Radiology Services</p> <ul style="list-style-type: none"> i) Description of how services are provided/obtained. ii) Procedures for requesting services. iii) X-ray equipment testing, registration iv) Incorporation of reports into the Medical Record v) Safety for patients and personnel (lead aprons, exposure badges) <p>f) Pharmacy Services</p> <ul style="list-style-type: none"> i) Description of how services are provided/obtained. ii) Procedures for requesting services <p>g) Other Services Not Available at the Center</p> <ul style="list-style-type: none"> i) Description of how services are provided/obtained. ii) Procedures for requesting services <p>h) Discharge Policies and Procedures:</p> <p>Discharge Order signed by the Physician.</p> <p>Verbal instructions confirmed by written instructions are provided at discharge that include at least the following:</p> <ul style="list-style-type: none"> i) Phone number to be used by the patient if complications or questions ii) Directions for medications prescribed iii) Date, time, and location of follow-up visit iv) Where to go in case of emergency 	
12	Transfer Agreements	<p>Plan and Procedure for the transfer of patients to a nearby hospital when hospitalization is indicated.</p> <ul style="list-style-type: none"> o Arrangements for an ambulance service include, when appropriate, escort of the patient to the hospital by an appropriate staff member. 	
13	List of Contracted Services	<ul style="list-style-type: none"> a) Pharmacist - Contract with Pharmacist b) Housekeeping c) Biohazard Removal d) Medical Record Consultant if applicable - (The Operator shall designate a staff member who has overall supervisory responsibility for the Medical Record System. The Operator shall ensure that the Medical Record Supervisor receives consultation from a qualified 	

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		<p>Medical Record Practitioner if the Supervisor is not a qualified Medical Record Practitioner.)</p> <ul style="list-style-type: none"> e) Preventive Maintenance (PM) Checks f) Linens g) Laboratory h) Social Worker 	
14	CLEP Laboratory Licenses	<ul style="list-style-type: none"> a) CLEP (Clinical Laboratory Evaluation Program) Laboratory Permit or Limited Service Laboratory Registration Certificate for tests performed onsite (e.g. fingerstick glucose, urine pregnancy). b) Routine and emergency tests performed at the facility or referred to a contracted NYS permitted laboratory) c) Procedures for requesting tests and obtaining blood, tissue and culture specimens with incorporation of reports into the Medical Record d) Pathology Report findings and tissue exemptions e) Policy for “ensuring prompt follow-up action on patients with abnormal test results” 	
15	Sample Admission Packet/Patient Brochure	Samples should include a copy of the actual Patient Rights information given to patient.	
16	Sample Clinical Record	<ul style="list-style-type: none"> a) Copy of Medical Record Content: (Sample of Clinical Record - TEMPLATE only). Including forms such as: <ul style="list-style-type: none"> o Fact Sheet o Allergies o Documentation that Patient Rights & Advance Directives were given. b) Medical Records must be stored in a place that can be locked and secured. c) Designated staff member who has overall supervisory responsibility (if the Medical Record Supervisor is not a qualified Medical Record Practitioner), is designated to ensure that the Medical Record Supervisor received consultation from a qualified Medical Record Practitioner Consultant. d) Retention, preservation and confidentiality (ADULTS: Retain for six (6) years minimum; MINORS: Retain for six (6) years past procedure or three (3) years past majority (whichever is longer). e) Procedure for sending a copy of pertinent parts of Medical Record, with patient’s consent, when patient is referred elsewhere f) Policy for granting patient access g) Prompt transfer of copy of pertinent parts of Medical Record when referred to facility or practitioner (e.g., if transferred to hospital) h) When treated with an outside healthcare provider that is relevant to the patient’s care, a clinical summary or other pertinent documents is obtained (e.g., if History and Physical is performed) 	

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		i) Release of records, as per Patient Rights.	
17	Sample Contract Audit Form	Submit a Sample of the Personnel Record - TEMPLATE only. Additional personnel Records will be reviewed onsite	
18	Sample Contracted Services Audit	Provide samples of forms or evidence of documentation that will be used to audit contracts and review contracted services. <ul style="list-style-type: none"> o Contracted services must be monitored, and contracts must be reviewed annually. 	

STEPS TO TAKE AFTER RECEIVING YOUR OPERATING CERTIFICATE

	<p>Health Commerce System (HCS)/Health Provider Network (HPN)</p>	<p>After receiving approval from DOH to open post pre-opening survey, the facility will receive an operating certificate (OC) that contains a 7-digit # followed by an “R”. This is the facility’s operating certificate # that is associated with the main site and extension clinics the operator oversees. In addition, the main site and their extension clinics (if any) will also have a four or five digit site-specific #.</p> <p>The Administrator/Director who oversees the day-to-day operations of the facility must complete the Health Commerce System (HCS) Access form and submit</p> <p><i>State Regulations 400.10</i></p> <ul style="list-style-type: none"> - Links below to HCS Access Form and instructions to start the process https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf - Link below to HCS Training and additional HCS Access Information https://www.health.ny.gov/facilities/hospital/connect_to_hcs_apps_and_training.htm 	
	<p>Incident Reporting (NYPORTS- New York Patient Occurrence Reporting Tracking System)</p>	<ul style="list-style-type: none"> • What to report. (Incidents, aka medical errors, adverse events) • When to report. • Where to report. <p><i>In the link below, see State Regulations 405.8 and 751.10, PHLs 2805-L & 2805-M and information and instructions on how to gain access to NYPORTS.</i></p> <p>https://www.health.ny.gov/facilities/hospital/nyports/</p>	<p>The NYPORTS application is available on the Health Commerce System (refer to Number 17 above of additional information).</p> <p>Access to HCS must be completed prior to requesting access to NYPORTS.</p>

Please Note: After the materials requested on this NYSECON Clinical Checklist are reviewed offsite, the onsite pre-opening survey will be conducted. All necessary equipment and supplies must be present at that time of the onsite survey, and the facility must be patient ready.

Please note: New Ambulatory Surgery Centers (ASCs) must obtain accreditation within two (2) full years of operation.

For new providers and providers changing ownership, Administrators **MUST** create a **Health Commerce System (HCS)** account specific to the health care facility. For guidance on how to acquire an HCS account for your facility, click the following link:

https://www.health.ny.gov/prevention/immunization/information_system/providers/hpn_account_instructions.htm

For NYS Regulations pertaining to free-standing Ambulatory Surgery Centers, refer to State Hospital Code:

Article 6: Diagnostic and Treatment Centers: NYCRR Title 10: Part 750, Part 751 (751.1 to 751.11), Subpart 752-1 (752-1.1 to 752-1.5) and Part 755 (755.1 to 755.10) available on our website at <https://www.health.ny.gov/facilities/hospital/>

For Federal requirements, please go to: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_1_ambulatory.pdf

Note: All policies and procedures in the Center Manual must be co-signed by the Medical Director and dated. The Center’s Policies and Procedures must be reviewed at least annually and revised as necessary.

#	Name of Documentation	Minimum Requirements	Guidance
1	Organizational Chart (delineating authority, to include but is not limited to):	<ul style="list-style-type: none"> a) Administrator b) Medical Director c) Director of Surgical Services (who is a Surgeon or Anesthesiologist and can also be the Medical Director) d) Director of Anesthesia (who can be the Medical Director, and is an Anesthesiologist) e) Director of Nursing (Licensed Registered Nurses responsible for Services in the Operating Room) f) Define who has authority over the Consultants (e.g. Pharmacy, Medical Record, Social Worker - if applicable) 	
2	Governing Authority Bylaws	<p>Operator -</p> <ul style="list-style-type: none"> a) Rules and Bylaws including selection of members, number of members needed for quorum; at least quarterly meetings (except if sole proprietor), committees (except if sole proprietor), and appointment of Department Directors must be developed. 	

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		<ul style="list-style-type: none"> o Responsibilities of the governing body including involvement in Quality Assurance and Performance Improvement (QAPI) and development of disaster preparedness plans o Meeting schedule <p>b) Scope of Services (list specific ambulatory surgical procedures) must be defined. The list of surgical procedures is maintained and reviewed at least biannually.</p> <p>c) Charity care - As required by NYCRR Title 10 Section 709.5 (d) 3 available at https://regs.health.ny.gov/content/section-7095-ambulatory-surgery-services</p>	
3	Medical Provider Bylaws and Rules	<p>a) Bylaws, Rules and Regulations of the Medical Staff - These Medical Bylaws are to be approved by the Operator. If Physician Assistants or Registered Specialist Assistants are being used, the Medical Bylaws are to include the provision of formal procedures for the evaluation of the application and credentials of Physician Assistants and Registered Specialist Assistants applying for privileges to provide medical services under a Physician's supervision.</p> <p>b) History & Physical Policy</p> <p>c) Physician Evaluation, Admission Assessment and Discharge Policies</p>	
4	Content of Medical Provider Credential and Quality Assurance File	<p>MDs and Mid-Levels</p> <ul style="list-style-type: none"> a) License b) Board Certification c) Delineation of privileges supported by recommendations d) Appointment Letter with Recredentialing Bi-Annually e) DEA (Drug Enforcement Administration) f) BCLS (Basic Cardiac Life Support) or ACLS/PALS (Advanced Cardiac Life Support / Pediatric Advanced Life Support) as per Emergency Protocol. g) Privileges at one (1) or more hospitals in the area h) Applications for admission to staff containing Statement of Training and Experience i) Evidence of ongoing Quality Review j) Evaluation of application & credentials of Mid-level Practitioners. k) Policy regarding oversight of Non-Physician Mid-Level Providers l) Evidence of Admitting Privileges at Medicare Participating Hospital or Local Non-Participating Hospital that provides Emergency Services m) Receipt of Bylaws 	Actual Credential Files for staff will be reviewed onsite. Submit a sample file - TEMPLATE Only
5	Content of all Staff Personnel and Health File	<p>a) All applicable staff</p> <ul style="list-style-type: none"> i) License ii) BCLS or ACLS/PALS as per emergency protocol iii) Orientation Skills Checklist - specific to job description and title (i.e. Nursing, Surgical Technologists, etc.) 	(Include MDs, RNs, Clerks, Mid-Level Practitioners, Techs, Nursing Assistants, etc.)

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> iv) Only RN is Circulating Nurse v) RN in charge of OR, PACU and Pre-Op vi) Requirements for Surgical Technologists are available in the 01/20/15 Dear Administrator Letter Surgical Technologists, accessible on the Department's website at https://www.health.ny.gov/professionals/hospital_administrator/letters/ Requirements for Central Service Technicians are available in the 01/21/15 Dear Administrator Letter regarding "Rules, Requirements and the Use of Central Service Technicians" and the 01/20/15 Dear CEO Letter accessible on the Department's website at https://www.health.ny.gov/professionals/hospital_administrator/letters/ <p>b) Health Files</p> <ul style="list-style-type: none"> i) Measles and Rubella Titers or proof of immunizations ii) Mantoux annually or chest X-ray (CXR) on file iii) Pre-Employment and Annual Health Exam iv) Rubeola (Post 1956) v) Influenza vi) Hepatitis B vii) Vaccine or declined 	
6	Staff Education and Training	<ul style="list-style-type: none"> a) Job Description for all staff with position requirements b) Evidence ASC provided copies of Policies regarding employment c) Evidence ASC Provided Orientation to Center's Policies d) Patient care responsibilities e) In services for DOH mandated courses on HIV Confidentiality and HIPAA/ Patient Rights/ Advance Directives/ Infection Control and Universal Precautions/ Fire Safety/ Child Abuse- Domestic Violence and Human Trafficking f) Advance Directives Policy g) Annual performance evaluations and competency assessments 	
7	Staffing Plan	<ul style="list-style-type: none"> a) Staffing Plan for each type of staff (MDs, Nurses, Techs, other) with list of names and staff titles b) Basic Staffing Pattern including supervision c) Hours of Operation 	
8	Quality Assurance Plan	<ul style="list-style-type: none"> a) The Operator who will develop and implement a written Quality Assurance (QA) Program. 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> b) The Operator will provide the QA Plan including oversight of technical operations and quality audits. c) The QA plan will identify the Medical Director who is responsible for the supervision of the QA Program and for reporting the activities of the Program to the Operator. d) QA Audit Plan which will specifically include the number of charts that will be reviewed and will define the timeframe in which the reviews will occur. The plan will include the indicators/review criteria (e.g., infections, complications) under Surgery/ Anesthesia/ Medical Record Documentation that will be used. e) Please specify: the responsibilities of participants; regularly scheduled reviews of Medical Records, Complaints and Incidents; participation by each professional service; findings and actions to be taken to resolve identified problems, and timely implementation of corrective actions with periodic assessments of the results of such actions and how information is provided to the Governing Body. f) Incident/Occurrence Reporting Policy and Incident types will include reporting timeframes. 	
9	Infection Control Plan	<ul style="list-style-type: none"> a) Name of the Infection Control Practitioner. b) Training requirements for the IC Nurse who must be designated to direct the Infection Control Program and includes hours spent in ASC Process for Risk Mitigation that is based on nationally recognized guidelines. c) Demonstrate how IC Guidelines are being used to follow national recognized IC Standards (CDC, AORN, APIC, SHEA). d) System used to actively identify infections related to procedures performed and documentation of tracking. e) How IC is incorporated into QAPI? f) Policies and Procedures (Based on National Standards) for: <ul style="list-style-type: none"> o Hand hygiene o Specific measures for MDROs (Multiple Drug Resistant Organisms) o Injection practices o Policy for cleaning glucometers o Multi-dose medications o Policy for reportable communicable diseases o Orientation of all new employees in IC and personal hygiene; with ongoing education in IC o Screening and surveillance of patients and HCWs (Health Care Workers) for risk of/actual infections and communicable diseases o Methods to minimize source & transmission of infection. Surgery related infection mitigation measures (for example antibiotic timing) o Active surveillance program o Provision for infected/contaminated patients 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> ○ Isolation Procedures ○ Recording incidents of post-op infections in log ○ Hazardous Waste Handling ○ Sterilization/autoclave spore-testing/validation single use devices (for reprocessed check FDA requirements) ○ Single use equipment ○ Offsite Sterilization Contract ○ Immediate use steam sterilization ○ Sterilizing equipment testing results ○ Separation of clean equipment/instrument storage ○ Patient follow up after discharge, tracking, documented in Medical Record ○ Resuscitative techniques (codes) ○ Aseptic technique and scrub procedures ○ Sterilization and disinfection procedures ○ Care of surgical specimens (see Laboratory Services below) ○ Surgical Procedure Protocols (including list of equipment, materials, supplies) ○ Cleaning of OR after each use ○ Acceptable OR attire ○ Care of anesthesia equipment ○ Special provision for infected or contaminated patients ○ Use of alcohol-based preparation ○ Needle stick injuries/potential HIV exposure ○ Blood Spills 	
10	Patient Emergency Plan	<p>Patient Emergency Policy specification of who (MD and RN) requires BCLS (basic life support)/ACLS (advanced life support)/PALS (pediatric advanced life support); (a practitioner qualified in resuscitation technique and emergency care must remain present until all patients are discharged).</p> <ul style="list-style-type: none"> a) Emergency protocol if patient codes (process; requirements of staff) b) Emergency equipment and supplies; contents of crash cart. (Emergency drugs and supplies as per Medical Staff {formulary by Anesthesia}) c) Emergency call system d) Generator testing e) Evacuation plan (fire) f) Disaster Preparedness Plan (coordination of plan with State and Local authorities as appropriate) g) All Code Policies h) Preventative maintenance on equipment i) Operation, security and maintenance of the Center 	

#	Name of Documentation	Minimum Requirements	Guidance
11	Operational and Clinical Policies and Procedures	<p>a) Nursing:</p> <ul style="list-style-type: none"> i) Frequency of Nursing monitoring in pre-op, intraoperatively, PACU (Post Anesthesia Care Unit) and prior to discharge. ii) Administration of blood and blood products iii) Medication administration iv) Medication errors v) Adverse reactions <p>b) Patient Rights Policies and Procedures:</p> <ul style="list-style-type: none"> i) Signage (All Waiting Rooms need signage) ii) Policy for distribution of Patient Rights and Advance Directives given with evidence documented in the Medical Record iii) Document in the Medical Record if the patient has a Health Care Proxy or not. iv) Grievance/Complaint Policy that includes that the facility investigates, providing a written response within thirty (30) days of findings of investigation (if requested by patient), and notifying patient that if they are not satisfied, they may complain to DOH, OPHSM v) Abuse and Neglect Policy vi) Exercise rights on behalf of a patient judged legally incompetent vii) Policy that addresses delegation by a patient to a representative viii) Communicating with patient with communication barrier ix) Child abuse reporting. x) Domestic Violence – Identification and treatment of victims xi) Surprise Bill Law xii) HIV Confidentiality xiii) HIPAA/Confidentiality xiv) Provision of service (details of nondiscrimination) xv) Informed Consent xvi) Human Trafficking xvii) Disclosure of physician financial interest or ownership <p>See Link below for Required Patient Rights publications https://www.health.ny.gov/professionals/patients/patient_rights/</p> <p>c) An Advance Directive Policy that Addresses the Following:</p> <ul style="list-style-type: none"> i) Provision of information to patients on Advance Directives <ul style="list-style-type: none"> o Policy for honoring or not, the patient’s Advance Directives for DNR (Do Not Resuscitate), if one is in the patient’s medical record. 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> ○ Ensure if transferred from the ASC to the hospital, that a copy of the Advance Directive is provided with the copy of the medical record when the patient is transferred. ○ The ASC must offer Advance Directive materials to the patient and must inform the patient in writing if the facility doesn't honor the Advance Directive such as a DNR). <p>d) Anesthesia Services Policies:</p> <ul style="list-style-type: none"> i) Pre-Anesthesia and Surgical Evaluation Policy that includes an assessment of patient and the anesthesia and procedural risks prior to every surgical procedure. <ul style="list-style-type: none"> ○ Must address the basis on which the patient is found to be suitable for the surgery and anesthesia. ○ How does patient selection criteria assure that there is an acceptable level of anesthesia and procedural risk? ○ Does the facility use patient admission criteria that excludes higher risk patients? ii) Criteria the Ambulatory Surgery Center's physicians will use in making the assessments and must assure consistency among assessments. iii) Time Out Procedure (verify right side, right site) iv) Intra-Op Form v) Post-Op Form vi) Post-Anesthesia Evaluation Policy that includes who conducts the post-surgical assessment (MD or RN with post-op experience) vii) Conscious sedation <p>e) Social Work Services:</p> <ul style="list-style-type: none"> i) Policy for evaluation of patients for medically related personnel and social problems ii) Staff member/position designated to coordinate with community services. iii) Referral to health-care facility or practitioner for service(s) not available at the Center <p>f) Radiology Services</p> <ul style="list-style-type: none"> i) Description of how services are provided/obtained. ii) Procedures for requesting services. iii) X-ray equipment testing, registration iv) Incorporation of reports into the Medical Record v) Safety for patients and personnel (lead aprons, exposure badges) <p>g) Pharmacy:</p>	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> i) All Medication Administration Policies (including labeling, disposal of discontinued or outdated and deteriorated drugs) ii) Adverse drug reactions reported to the physician iii) Policy for Management of Malignant Hyperthermia iv) Verbal order <p>h) Discharge Policies and Procedures: Discharge Order signed by the Physician who performed the surgery or procedure. Verbal instructions confirmed by written instructions are provided at discharge that include at least the following:</p> <ul style="list-style-type: none"> i) Information about possible complications ii) Phone number to be used by the patient if complications or questions iii) Directions for medications prescribed iv) Date, time, and location of follow-up visit v) Where to go in case of emergency vi) Discharge with responsible adult 	
12	Transfer Agreements	Plan and Procedure for the transfer of patients to a nearby hospital when hospitalization is indicated. <ul style="list-style-type: none"> o Arrangements for an ambulance service and include, when appropriate, escort of the patient to the hospital by an appropriate staff member. 	
13	List of Contracted Services	<ul style="list-style-type: none"> a) Pharmacist - Contract with Pharmacist b) Housekeeping c) Biohazard Removal d) Medical Record Consultant if applicable - (The Operator shall designate a staff member who has overall supervisory responsibility for the Medical Record System. The Operator shall ensure that the Medical Record Supervisor receives consultation from a qualified Medical Record Practitioner if the Supervisor is not a qualified Medical Record Practitioner.) e) Preventive Maintenance (PM) Checks f) Linens g) Laboratory h) Social Worker 	
14	CLEP Laboratory Licenses	<ul style="list-style-type: none"> a) CLEP (Clinical Laboratory Evaluation Program) Laboratory Permit or Limited Service Laboratory Registration Certificate for tests performed onsite (e.g. fingerstick glucose, pregnancy). 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> b) Routine and emergency tests performed at the facility or referred to a contracted NYS permitted laboratory) c) Procedures for requesting tests and obtaining blood, tissue and culture specimens with incorporation of reports into the Medical Record d) Pathology Report findings and tissue exemptions e) Policy for “ensuring prompt follow-up action on patients with abnormal test results” 	
15	Sample Admission Packet/Patient Brochure	Samples should include a copy of the actual Patient Rights information given to patient.	
16	Sample Clinical Record	<ul style="list-style-type: none"> a) Copy of Medical Record Content: (Sample of Clinical Record - TEMPLATE only). Including forms such as: <ul style="list-style-type: none"> o Fact Sheet o Allergies o Documentation that Patient Rights & Advance Directives were given. o Informed Consents for Anesthesia and Surgical o Consent for Anesthesia: Please state the name of the Anesthesiologist and the proposed anesthesia o History & Physical less than thirty (30) days before surgery o Pre-Surgical Assessment immediately before surgery indicating changes o Op Reports o Medication Reconciliation Form o Time Out Form b) Medical Records storage must be in a place that can be locked and secured. c) Designated staff member who has overall supervisory responsibility (if the Medical Record Supervisor is not a qualified Medical Record Practitioner), is designated to ensure that the Medical Record Supervisor received consultation from a qualified Medical Record Practitioner Consultant. d) Retention, preservation and confidentiality (ADULTS: Retain for six (6) years minimum; MINORS: Retain for six (6) years past procedure or three (3) years past majority (whichever is longer). e) Procedure for sending a copy of pertinent parts of Medical Record, with patient’s consent, when patient is referred elsewhere f) Policy for granting patient access g) Prompt transfer of copy of pertinent parts of Medical Record when referred to facility or practitioner (- e.g., if transferred to hospital) h) When treated with an outside healthcare provider that is relevant to the patient’s care, a clinical summary or other pertinent documents is obtained (e.g., if History and Physical is performed) i) Release of records, as per Patient Rights. 	

#	Name of Documentation	Minimum Requirements	Guidance
17	Sample Personnel Record	Submit a Sample of a Personnel Record – TEMPLATE Only. Additional personnel Records will be reviewed onsite	
18	Sample Contract Audit Form	Provide samples of forms or evidence of documentation that will be used to audit contracts and review contracted services. <ul style="list-style-type: none"> o Contracted services must be monitored, and contracts must be reviewed annually. 	

STEPS TO TAKE AFTER RECEIVING YOUR OPERATING CERTIFICATE

	855 B-Medicare Enrollment Form <i>(Please be reminded that the facility name on the 855 B form <u>must match</u> the name on the operating certificate.)</i>	<p>After facility has approval to open, the 855-B Enrollment form must be submitted to the Medicare Administrative Contractor (MAC).</p> <p>For additional information regarding the Medicare enrollment process, including Internet-based PECOS, go to www.cms.gov/MedicareProviderSupEnroll.</p>	
	Health Commerce System (HCS)/Health Provider Network (HPN)	<p>After receiving approval from DOH to open post pre-opening survey, the facility will receive an operating certificate (OC) that contains a 7-digit # followed by an “R”. This is the facility’s operating certificate # that is associated with the main site and extension clinics the operator oversees. In addition, the main site and their extension clinics (if any) will also have a four or five digit site-specific #.</p> <p>The Administrator/Director who oversees the day-to-day operations of the facility must complete the Health Commerce System (HCS) Access form and submit</p> <p><i>State Regulations 400.10</i></p> <ul style="list-style-type: none"> - Links below to HCS Access Form and instructions to start the process https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf - Link below to HCS Training and additional HCS Access Information https://www.health.ny.gov/facilities/hospital/connect_to_hcs_apps_and_training.htm 	
	INCIDENT REPORTING (NYPORTS- New York Patient Occurrence Reporting Tracking System)	<ul style="list-style-type: none"> • What to report. (Incidents, aka medical errors, adverse events) • When to report. • Where to report. <p><i>In the link below, see State Regulations 405.8 and 751.10, PHLs 2805-L & 2805-M and information and instructions on how to gain access to NYPORTS.</i></p> <p>https://www.health.ny.gov/facilities/hospital/nyports/</p>	<p>The NYPORTS application is available on the Health Commerce System (refer to Number 17 above of additional information).</p> <p>Access to HCS must be completed prior to requesting access to NYPORTS.</p>

Please Note: After the materials requested on this NYSECON Clinical Checklist are reviewed offsite, the onsite pre-opening survey will be conducted. All necessary equipment and supplies must be present at that time of the onsite survey, and the facility must be patient ready.

For new providers and providers changing ownership, Administrators **MUST** create a **Health Commerce System (HCS)** account specific to the health care facility. For guidance on how to acquire an HCS account for your facility, click the following link:

https://www.health.ny.gov/prevention/immunization/information_system/providers/hpn_account_instructions.htm

For NYS Regulations pertaining to free-standing Diagnostic and Treatment Centers (Clinics), which include ESRDs, refer to State Hospital Code:

Article 6: Diagnostic and Treatment Centers: NYCRR Title 10: Part 750, Part 751 (751.1 to 751.11), Subpart 752-1 (752-1.1 to 752-1.5) and Part 757 (757.1 to 757.3) available on our website at <https://www.health.ny.gov/facilities/hospital/>

Note: All policies and procedures in the Center Manual must be co-signed by the Medical Director and dated. The Center’s Policies and Procedures must be reviewed at least annually and revised as necessary.

#	Name of Documentation	Minimum Requirements	Guidance
1	Organizational Chart (delineating authority, to include but is not limited to):	<ul style="list-style-type: none"> a) Administrator b) Medical Director c) Director of Nursing d) Define who has authority over the Consultants (e.g. Pharmacy, Medical Record, Social Worker - if applicable) 	
2	Governing Authority Bylaws	<p>Operator -</p> <ul style="list-style-type: none"> a) Rules and Bylaws including selection of members, number of members needed for quorum; at least quarterly meetings (except if sole proprietor), committees (except if sole proprietor), and appointment of Department Directors must be developed. <ul style="list-style-type: none"> o Responsibilities of the governing body including involvement in Quality Assurance and Performance Improvement (QAPI) and 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> development of disaster preparedness plans. <ul style="list-style-type: none"> o Meeting schedule b) Scope of Services and Purpose of the Center 	
3	Medical Provider Bylaws and Rules	<ul style="list-style-type: none"> a) Bylaws, Rules and Regulations of the Medical Staff - These Medical Bylaws are to be approved by the Operator. If Physician Assistants or Registered Specialist Assistants are being used, the Medical Bylaws are to include the provision of formal procedures for the evaluation of the application and credentials and recredentialing of Physician Assistants and Registered Specialist Assistants applying for privileges to provide medical services under a Physician's supervision. b) History & Physical Policy c) Physician Evaluation, Admission Assessment and Discharge/Involuntary Discharge Policies <ul style="list-style-type: none"> o Development of comprehensive care plan including evaluation and monitoring of patients on the transplant list o Initial and renewal of patient orders o Inform patients about the ESRD network and provide contact information for the ESRD network. 	
4	Content of Medical Provider Credential / Privilege and Quality Assurance File	MDs and Mid-Levels - <ul style="list-style-type: none"> a) License b) Board Certification c) Delineation of privileges supported by recommendations d) Appointment Letter with Recredentialing Bi-Annually e) DEA (Drug Enforcement Administration) license f) BCLS (Basic Cardiac Life Support) or ACLS/PALS (Advanced Cardiac Life Support / Pediatric 	Actual Credential Files for staff will be reviewed onsite. Submit a sample file - TEMPLATE Only.

#	Name of Documentation	Minimum Requirements	Guidance
		<p>Advanced Life Support) as per Emergency Protocol</p> <ul style="list-style-type: none"> g) Applications for admission to staff containing Statement of Training and Experience h) Evidence of ongoing Quality Review i) Evaluation of application & credentials of Mid-level Practitioners. j) Policy regarding oversight of Non-Physician Mid-Level Providers k) Receipt of Bylaws 	
5	Content of all Staff Personnel File	<ul style="list-style-type: none"> a) All applicable staff <ul style="list-style-type: none"> i) License ii) BCLS or ACLS/PALS as per emergency protocol iii) Orientation Skills Checklist - specific to job description and title (i.e. Nursing, Surgical Technologists, etc.) b) Health Files <ul style="list-style-type: none"> i) Measles and Rubella Titers or proof of immunizations ii) Mantoux annually or chest X-ray (CXR) on file iii) Pre-Employment and Annual Health Exam iv) Rubeola (Post 1956) v) Influenza vi) Hepatitis B vii) Vaccine or declined 	(Include MDs, RNs, Clerks, Mid-Level Practitioners, Techs, Nursing Assistants, etc.)
6	Staff Education and Training	<ul style="list-style-type: none"> a) Job Description for all staff with position requirements b) Evidence that the facility provided copies of policies regarding employment c) Evidence that the facility provided orientation to staff on facility's policies d) Patient care responsibilities e) In services for DOH mandated courses on HIV Confidentiality and HIPAA/ Patient Rights/ Advance Directives/ Infection Control and 	

#	Name of Documentation	Minimum Requirements	Guidance
		Universal Precautions/ Fire Safety/ Child Abuse- Domestic Violence and Human Trafficking f) Advance Directives Policy g) Annual performance evaluations and competency assessments	
7	Staffing Plan	a) Staffing Plan for each type of staff (MDs, Nurses, Techs, other) with list of names and staff titles b) Basic Staffing Pattern including supervision c) Hours of Operation	
8	Quality Assurance Plan	a) The Operator will develop and implement a written Quality Assurance (QA) Program including Home Hemodialysis and Peritoneal Dialysis. b) The Operator will provide the QA Plan including oversight of technical operations and quality audits. c) The QA plan will identify the Medical Director who is responsible for the supervision of the QA Program and for reporting the activities of the Program to the Operator. d) QA Audit Plan which will specifically include the number of charts that will be reviewed and will define the timeframe in which the reviews will occur. The plan will include the indicators/review criteria that will be used. e) Please specify: the responsibilities of participants; regularly scheduled reviews of Medical Records, Complaints and Incidents; participation by each professional service; findings and actions to be taken to resolve identified problems, and timely implementation of corrective actions with periodic assessments of the results of such actions and how information gets to the Governing Body.	

#	Name of Documentation	Minimum Requirements	Guidance
		f) Incident/Occurrence Reporting Policy and Incident types will include reporting timeframes.	
9	Infection Control Plan	a) Name of the Infection Control (IC) Practitioner. b) Training requirements for the IC Nurse who must be designated to direct the IC Program and includes hours spent in the ESRD Process for Risk Mitigation that is based on nationally recognized guidelines. c) Demonstrate how IC Guidelines are being used to follow national recognized IC Standards (CDC, APIC, etc.). d) System used to actively identify infections related to procedures performed and documentation of tracking. e) How IC is incorporated into QAPI? f) Policies and Procedures (Based on National Standards) for: <ul style="list-style-type: none"> o Hand hygiene o Specific measures for MDROs (Multiple Drug Resistant Organisms) o Injection practices o Policy for cleaning glucometers o Multi-dose medications o Policy for reportable communicable diseases o Orientation of all new employees in IC and personal hygiene; with ongoing education in IC o Screening and surveillance of patients and HCWs (Health Care Workers) for risk of/actual infections and communicable diseases o HIV Infection Control o Hepatitis screening, vaccination and tracking (for surveillance purposes to identify immune and susceptible patients) o Influenza vaccination and tracking o Pneumococcal vaccination and tracking 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> ○ Methods to minimize source & transmission of infection ○ Active surveillance program ○ Cannulation procedures – catheter, graft and fistula ○ Provision for infected or contaminated patients ○ Isolation Procedures ○ Hazardous Waste Handling ○ Sterilization/autoclave spore-testing/validation single use devices (for reprocessed check FDA requirements), if in use onsite ○ Single use equipment ○ Offsite Sterilization Contract ○ Sterilizing equipment testing results ○ Separation of clean equipment/instrument storage ○ Patient follow up after discharge, tracking, documented in Medical Record ○ Resuscitative techniques (codes) ○ Needle stick injuries/potential HIV exposure ○ Blood Spills 	
10	Patient Emergency Plan	<p>Patient Emergency Policy specification of who (MD, Mid-Levels, RN, etc.) requires BCLS (basic life support)/ACLS (advanced life support)/PALS (pediatric advanced life support); (a practitioner qualified in resuscitation technique and emergency care must remain present until all patients are discharged).</p> <ul style="list-style-type: none"> a) Emergency protocol if patient codes (process; requirements of staff) b) Emergency equipment and supplies; contents of crash cart. (Emergency drugs and supplies as per Medical Staff {formulary by Anesthesia}) c) Emergency call system d) Generator testing, if facility has a generator 	<p>Link to Environmental Documentation Checklist (EDC) https://www.health.ny.gov/facilities/construction_notices/docs/environmental_documentation_checklist.pdf</p>

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> e) Evacuation plan (fire) f) Disaster Preparedness Plan (coordination of plan with State and Local authorities as appropriate) g) All Code Policies h) Preventative maintenance on equipment i) Operation, security and maintenance of the facility 	
11	Operational and Clinical Policies and Procedures	<ul style="list-style-type: none"> a) Nursing: <ul style="list-style-type: none"> i) Frequency of nursing monitoring and prior to discharge ii) Medication administration iii) Medication errors iv) Adverse reactions b) Patients' Rights Policies & Procedures <ul style="list-style-type: none"> i) Signage (All Waiting Rooms require signage) ii) Policy for distribution of Patient Rights and Advance Directives given with evidence documented in the Medical Record iii) Document in the Medical Record if the patient has a Health Care Proxy or not. iv) Grievance/Complaint Policy that includes that the facility investigates, providing a written response within thirty (30) days of findings of investigation (if requested by patient), and notifying patient that if they are not satisfied, they may complain to DOH, OPHSM v) Abuse and Neglect Policy vi) Exercise rights on behalf of a patient judged legally incompetent vii) Policy that addresses delegation by a patient to a representative viii) Communicating with patient with communication barrier ix) Child abuse reporting 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> x) Domestic Violence – Identification and treatment of victims xi) Surprise Bill Law xii) HIV Confidentiality xiii) HIPAA/Confidentiality xiv) Provision of service (details of nondiscrimination) xv) Informed Consent xvi) Human Trafficking xvii) Patient is provided with information to inform him/her of the various treatment modalities <p>See Link below for Required Patient Rights publications https://www.health.ny.gov/professionals/patients/patient_rights/</p> <p>c) An Advance Directive Policy that Addresses the Following:</p> <ul style="list-style-type: none"> i) Provision of information to patients on Advance Directives <ul style="list-style-type: none"> o Policy for honoring or not, the patient’s Advance Directives for DNR (Do Not Resuscitate), if one is in the patient’s medical record. o Ensure if the patient is transferred to the hospital that a copy of the Advanced Directive is provided with the copy of the medical record when the patient is transferred. <p>d) Social Work Services:</p> <ul style="list-style-type: none"> i) Must be directed by a licensed social worker or a licensed masters social worker. ii) Policy for evaluation of patients for medically related personnel and social problems iii) Staff member/position designated to coordinate with community services. 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> iv) Referral to health-care facility or practitioner for service(s) not available at the facility v) Social work services are provided to all patients on an on-going basis. e) Nursing Care Procedures that address: <ul style="list-style-type: none"> i) Hemodialysis ii) Home dialysis (if provided) iii) Medication administration iv) Medication errors v) Epogen administered at home vi) Adverse reactions f) Nutritional Services <ul style="list-style-type: none"> i) Registered dietician must hold the Commission on Dietetic Registration. ii) Description of how services are provided/obtained. iii) Procedures for requesting services iv) Dietary services are available to all patients on an ongoing basis. g) Other Services Not Available at the Center <ul style="list-style-type: none"> i) Description of how services are provided/obtained. ii) Procedures for requesting services h) Water and Dialysate Procedures that address: <ul style="list-style-type: none"> i) Water treatment and dialysate ii) Instrument/machine maintenance including biological and chemical acceptability iii) Water testing iv) Re-use (if applicable) 	
12	Transfer Agreements	<p>Plan and Procedure for the transfer of patients to a nearby hospital when hospitalization is indicated.</p> <ul style="list-style-type: none"> o Arrangements for an ambulance service and include, when appropriate, escort of the patient to the hospital by an appropriate staff member. 	

#	Name of Documentation	Minimum Requirements	Guidance
13	List of Contracted Services	<ul style="list-style-type: none"> a) Pharmacist - Contract with Pharmacist b) Housekeeping c) Biohazard Removal d) Medical Record Consultant if applicable <ul style="list-style-type: none"> o The Operator shall designate a staff member who has overall supervisory responsibility for the Medical Record System. o The Operator shall ensure that the Medical Record Supervisor receives consultation from a qualified Medical Record Practitioner if the Supervisor is not a qualified Medical Record Practitioner. e) Preventive Maintenance (PM) Checks f) Linens g) Laboratory h) Social Worker 	
14	CLEP Laboratory Licenses	<ul style="list-style-type: none"> a) CLEP (Clinical Laboratory Evaluation Program) Laboratory Permit or Limited Service Laboratory Registration Certificate for tests performed onsite (e.g. fingerstick glucose). b) Routine and emergency tests performed at the facility or referred to a contracted NYS permitted laboratory) c) Procedures for requesting tests and obtaining blood, tissue and culture specimens with incorporation of reports into the Medical Record d) Pathology Report findings and tissue exemptions e) Policy for “ensuring prompt follow-up action on patients with abnormal test results” 	
15	Sample Admission Packet/Patient Brochure	Samples should include a copy of the actual Patient Rights information given to patient.	
16	Sample Clinical Record	<ul style="list-style-type: none"> a) Copy of Medical Record Content: (Sample of Clinical Record - TEMPLATE only). Including forms such as: 	

#	Name of Documentation	Minimum Requirements	Guidance
		<ul style="list-style-type: none"> ○ Fact Sheet ○ Allergies ○ Documentation that Patient Rights & Advance Directives were given. ○ Informed Consents for Anesthesia and Surgical ○ Consent for Anesthesia: Please state the name of the Anesthesiologist and the proposed anesthesia ○ History & Physical less than thirty (30) days before surgery ○ Pre-Surgical Assessment immediately before surgery indicating changes ○ Op Reports ○ Medication Reconciliation Form ○ Time Out Form <p>b) Medical Records storage must be in a place that can be locked and secured.</p> <p>c) Designated staff member who has overall supervisory responsibility (if the Medical Record Supervisor is not a qualified Medical Record Practitioner), is designated to ensure that the Medical Record Supervisor received consultation from a qualified Medical Record Practitioner Consultant.</p> <p>d) Retention, preservation and confidentiality (ADULTS: Retain for six (6) years minimum; MINORS: Retain for six (6) years past procedure or three (3) years past majority (whichever is longer).</p> <p>e) Procedure for sending a copy of pertinent parts of Medical Record, with patient's consent, when patient is referred elsewhere</p> <p>f) Policy for granting patient access</p> <p>g) Prompt transfer of copy of pertinent parts of Medical Record when referred to facility or practitioner (- e.g., if transferred to hospital)</p> <p>h) When treated with an outside healthcare provider that is relevant to the patient's care, a clinical summary or other pertinent documents</p>	

#	Name of Documentation	Minimum Requirements	Guidance
		<p>is obtained (e.g., if History and Physical is performed)</p> <p>i) Release of records, as per Patient Rights.</p>	
17	Sample Personnel Record	Submit a Sample of a Personnel Record – TEMPLATE Only. Additional personnel Records will be reviewed onsite.	
18	Sample Contract Audit Form	<p>Provide samples of forms or evidence of documentation that will be used to audit contracts and review contracted services.</p> <ul style="list-style-type: none"> ○ Contracted services must be monitored, and contracts must be reviewed annually. 	

STEPS TO TAKE AFTER RECEIVING YOUR OPERATING CERTIFICATE

	<p>855 B-Medicare Enrollment Form <i>(Please be reminded that the facility name on the 855 B form <u>must match</u> the name on the operating certificate.)</i></p>	<p>After facility has approval to open, the 855-B Enrollment form must be submitted to the Medicare Administrative Contractor (MAC) and cannot be submitted until the State licensure process has occurred and the facility has opened and is providing services to at least one patient for each modality offered.</p> <p>For additional information regarding the Medicare enrollment process, including Internet-based PECOS, go to www.cms.gov/MedicareProviderSupEnroll.</p> <p>Electronic Code of Federal Regulations - Part 494 - Conditions of Coverage for ESRD facilities https://www.ecfr.gov/cgi-bin/text-idx?SID=20b01acd4992abab2f635cfd395f4114&no-de=pt42.5.494&rgn=div5</p>	<p>After approval of the 855-A Enrollment form, the facility must submit the CMS 3427 to the Department’s Regional Office to request a certification survey.</p>
	Health Commerce System (HCS)/Health Provider Network (HPN)	<p>After receiving approval from DOH to open post pre-opening survey, the facility will receive an operating certificate (OC) that contains a 7-digit # followed by an “R”. This is the facility’s operating certificate # that is associated with the main site and extension clinics the operator oversees. In addition, the main site and their extension clinics</p>	

#	Name of Documentation	Minimum Requirements	Guidance
		<p>(if any) will also have a four or five digit site-specific #.</p> <p>The Administrator/Director who oversees the day-to-day operations of the facility must complete the Health Commerce System (HCS) Access form and submit</p> <p><i>State Regulations 400.10</i></p> <ul style="list-style-type: none"> - Links below to HCS Access Form and instructions to start the process https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf - Link below to HCS Training and additional HCS Access Information https://www.health.ny.gov/facilities/hospital/connect_to_hcs_apps_and_training.htm 	
	<p>INCIDENT REPORTING (NYPORTS- New York Patient Occurrence Reporting Tracking System)</p>	<ul style="list-style-type: none"> • What to report. (Incidents, aka medical errors, adverse events) • When to report. • Where to report. <p><i>In the link below, see State Regulations 405.8 and 751.10, PHLs 2805-L & 2805-M and information and instructions on how to gain access to NYPORTS.</i></p> <p>https://www.health.ny.gov/facilities/hospital/nyports/</p>	<p>The NYPORTS application is available on the Health Commerce System (refer to Number 17 above of additional information).</p> <p>Access to HCS must be completed prior to requesting access to NYPORTS.</p>

Websites for State and Federal Regulations Related to ESRDs:

<http://www.ecfr.gov/cgi-bin/text-idx?SID=20b01acd4992abab2f635cfd395f4114&node=pt42.5.494&rgn=div5>

State Operations Manual **Appendix Z** – Emergency Preparedness

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf

<https://regs.health.ny.gov/content/part-750-general-provisions>

<https://regs.health.ny.gov/content/part-751-organization-and-administration>

<https://regs.health.ny.gov/content/subpart-752-1-center-services>

<https://regs.health.ny.gov/volume-d-title-10/242506745/part-757-chronic-renal-dialysis-services>

<https://regs.health.ny.gov/content/section-40021-advance-directives>

<https://regs.health.ny.gov/content/section-40020-hiv-infection-control>

<https://regs.health.ny.gov/content/section-40010-health-provider-network-access-and-reporting-requirements>

Patient Rights Publications to Inform Patients of their Rights as a Patient in a Clinic and in a Hospital

Patients' Bill of Rights for Diagnostic & Treatment Centers <https://www.health.ny.gov/publications/1515/>

Your Rights as a Hospital Patient in New York State booklet - <https://www.health.ny.gov/publications/1449.pdf>

(Via DAL-19-01 in Link below, recommends offering the booklet to patients along with the **Patient Bill of Rights for Clinics (#1515)**).

https://www.health.ny.gov/professionals/hospital_administrator/letters/2019/docs/dal_19-01_dhdtc.pdf