

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL092-776	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 02/25/2019
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NAME OF PROVIDER OR SUPPLIER SIGMA HEALTH SERVICES, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 2321 CRABTREE BOULEVARD, SUITE 250 RALEIGH, NC 27604
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
V 000	INITIAL COMMENTS An annual and complaint survey was completed on 2/25/19. The complaint was substantiated Intake NC00145335. A deficiency was cited. This facility is licensed for the following service categories: 10A NCAC 27G .4400 Substance Abuse Intensive Outpatient Program and 10A NCAC 27G .4500 Substance Abuse Comprehensive Outpatient Treatment	V 000	27G.0203 Privileging /Training Professionals Sigma Health Services (SHS) will require training provided by the new testing company Paradigm for all staff members. Clinical Director will provide training in SHS policies and procedures (P-4) regarding competencies.	April '19
V 109	27G .0203 Privileging/Training Professionals 10A NCAC 27G .0203 COMPETENCIES OF QUALIFIED PROFESSIONALS AND ASSOCIATE PROFESSIONALS (a) There shall be no privileging requirements for qualified professionals or associate professionals. (b) Qualified professionals and associate professionals shall demonstrate knowledge, skills and abilities required by the population served. (c) At such time as a competency-based employment system is established by rulemaking, then qualified professionals and associate professionals shall demonstrate competence. (d) Competence shall be demonstrated by exhibiting core skills including: (1) technical knowledge; (2) cultural awareness; (3) analytical skills; (4) decision-making; (5) interpersonal skills; (6) communication skills; and (7) clinical skills. (e) Qualified professionals as specified in 10A NCAC 27G .0104 (18)(a) are deemed to have met the requirements of the competency-based employment system in the State Plan for MH/DD/SAS. (f) The governing body for each facility shall	V 109	SHS will explore the feasibility of having a lab representative from Paradigm on site to provide testing. The Intake Specialist will be trained as the primary staff responsible for UDT collection. The backup for collections will be the therapist conducting SAIOP classes. The Clinical Director will supervise the training of the staff members and will provide a 3 month review of adherence to SHS policies and procedures. SHS will follow the best practices for UDT including staff accompanying client to the bathroom, random testing, and putting the collected samples in a secure location.	March '19 April '19 June '19 April '19

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

DHSR-Mental Health

MAR 18 2019

Lic. & Cert. Section

Jo. W. P. TITLE
CEO, MBA
Executive Director

(X6) DATE
03/11/2019

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develop and implement policies and procedures for the initiation of an individualized supervision plan upon hiring each associate professional. (g) The associate professional shall be supervised by a qualified professional with the population served for the period of time as specified in Rule .0104 of this Subchapter.

This Rule is not met as evidenced by:
Based on observation, record review and interview the facility failed to ensure 2 of 3 audited staff (intake specialist & SAIOP facilitator) demonstrated the knowledge and skills required by the population served. The findings are:

Observation on 2/15/19 revealed the following:

- 11:10am revealed an African American lady come in the office area with a cup of urine...there was no staff that accompany her...surveyor was not able to visually see where she took the urine - 11:47am - the bathroom was located in a hallway outside of where the SAIOP services were provided
- at 12:27pm - there was a white plastic storage box that contained urine samples under a table in the intake specialist office...8 total urine samples were in the box...3 of the urine samples were without names
- the Executive Director witnessed the urine samples without names on them

During interview on 2/15/19 client #1 reported: -
urine samples are taken every Monday -
clients are responsible for placing their names on the urine sample...she forgot to put her name on the urine sample this morning

The Intake Specialist and SAIOP Facilitator will be monitored for the next 3 months and a monthly report will be forwarded to the Executive Director for review.

June '19

The SAIOP facilitator and the Intake Specialist each have received disciplinary counseling forms for them not following UDT protocols. Along with ongoing trainings monthly, quarterly, and bi-annual.

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<p>V 109</p>	<p>Continued From page 2</p> <ul style="list-style-type: none"> - urine samples are not observed by staff - after she completes the urine sample it was placed in a box in the intake specialist office <p>During interview on 2/15/19 client #2 reported:</p> <ul style="list-style-type: none"> - urine samples were not observed by staff - clients are responsible for placing their names on the urine samples <p>During interview on 2/15/19 the Intake Specialist reported:</p> <ul style="list-style-type: none"> - the SAIOP facilitator was responsible for placing the clients name on the urine sample cup & accompanying them to the bathroom - most of the time the clients are self-sufficient and go to the bathroom alone for the urine samples - the urine was placed in the white plastic storage box in her office - she would throw the urine samples away without the names on them <p>During interview on 2/15/19 the SAIOP facilitator reported:</p> <ul style="list-style-type: none"> - clients write their initials on the urine sample cup - clients are supposed to go to the bathroom with staff to give urine sample - she thought the intake specialist ensured the clients' initials were on the urine samples since the urine samples were kept in her office <p>During interview on 2/25/19 the Executive Director reported:</p> <ul style="list-style-type: none"> - staff are supposed to accompany the clients to the bathroom for urine samples - he normally accompanied the males to the bathroom - initially the intake specialist was responsible for ensuring the initials were on the urine samples 	<p>V 109</p>		
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V 109	Continued From page 3 and then it changed to the SAIOF facilitator - it was some discussion about having a lab representative onsite to collect the urine samples - in the future it will be one designated person responsible for the collection of urine samples	V 109	Please see enclosed Paradigm UDT procedures.	



PARADIGM

NO POINT-OF-CARE TESTING

Urine Specimens are potentially infectious. Proper handling and disposal methods should be followed. Avoid contact with skin by wearing proper personal protection equipment.

THINGS YOU SHOULD KNOW ABOUT SPECIMAN COLLECTION & HANDLING

- ❖ A fresh urine specimen should be collected in the container provided. Alternately, you can provide a patient with a commode hat to assist with collection of urine and move it over into the collection cup.



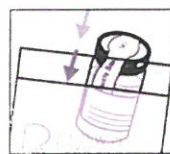
WHAT YOU WILL NEED TO COLLECT A SPECIMEN- Clean, Dry, untampered clear cup, 1 Biohazard bag, 1 complete req form, sharpie marker and patient willing to provide the sample.

- CLEARLY print patient's 1st initial & last name with sharpie on cup & date of birth on the lid of the cup
- Have patient verify the information on the cup is correct
- Patient provides the proper amount of urine in the cup & returns it to you
- CLEARLY Print the patient's name & date of collection on the label at top of req form
- Using your gloves- firmly secure the lid to the cup to prevent leaking
- Remove sticker from req form & place it on the cup leaving all information visible on cup & label
- The Patient MUST SIGN section 4 at this time if they have not already done so

PACKAGE AND SHIPPING SPECIMEN- you will need UPS or FED EX packing supplies with labels

Quick QUALITY CONTROL of your samples before packing & shipping

- Verify the LID IS SECURE on the cup
- Verify cup has ALL the identifiers on it- 1st initial last name DOB on cup & name & date of collection on label
- Verify the requisition form has all the sections complete – do you have a complete patient demographic? Do you have clear copy of insurance card front & back? Do you have all workers comp required information?
- Fold first page of req form with all demographic & insurance info and place in the paperwork pouch of baggy
- Place cup in the pocket with the absorbent square and seal the baggy completely



Place the baggies in the Clinical LabPak for UPS or FED EX – use the shipping boxes if provided.



PARADIGM

Quality Control Protocol Preparing and Shipping Samples

Following the instructions below will avoid delays in laboratory results.

Please verify each check box as you follow the instructions below:

1. Preparing Samples

- Is the lid on the cup threaded correctly and closed tightly?!!***
- Are there at least (2) patient identifiers on the cup?**
 - Use Specimen ID Label on paper req., or Barcode Label for Online req.
 - * Full name or First initial Full last name- PREFERRED METHOD
 - * Initials (First. Last.; use a period between) OR (Last, First; use comma between)
 - * Date of Birth-matches paperwork provided
 - * Specimen (cup) ID# must match Requisition ID#
- EREQ clients-** is there an order? Has it been approved? Have you printed the form & placed the 3 labels correctly-
1 on the matching cup - 1 on the matching signature page - 1 on a packing list
- Are ALL sections of the PAPER requisition form completed?**
 - Patient information correct - Doctor's signature on form
 - Handwriting MUST be legible
- Are the orders marked clearly on the PAPER requisition?**
 - The check boxes must be clearly marked
- Are the demographics, meds list and insurance info included? Is it a clear copy?**
- Place WHITE (original) with patient's signature- copy of requisition with demographics, med list, and insurance info OR eREQ signature form in SLEEVE of specimen bag.**
- Place PINK copy of paper requisition in separate bundle stacks**
- Place matching sample cup in the Ziploc section of specimen bag- seal the zip lock section**

What will Place the sample on HOLD?

- No orders selected on the requisition form or in LabOnline for sample
- Missing info on paper requisition form (date of birth, practitioner name, date of collection)
- Illegible handwriting
- No doctor signature on file or on requisition form or STAMP of signature

What will REJECT the sample?

- No identifiers on the cup.
 - This is usually only (1) identifier, or none at all.
- Mismatched information.
 - Information on paper req or eREQ signature form does not match identifiers on cup
 - If all (3) identifiers are used, all (3) must match for requisition and cup
- On HOLD for 21 days
If a sample is placed on hold, the sample must be resolved within 21 days
- Use of white-out on paper req form, eREQ signature page or on cups

THE MISSION is to get each sample to the lab and each result back to the provider as quickly as possible without causing more than necessary work on any one part of the "FIELD to LAB back to FIELD" process. It is all about the patient and the important information that urine sample holds for the provider.



Quality Control Protocol Preparing and Shipping Samples

2. Shipping Samples

*****UPS & FedEx SHIPPING BAGS safely hold up to 10 samples. We recommend shipping the labpaks in boxes to protect samples from being crushed.**

- Number your shipping bag(s) for that day (1-10 etc.)
- EREQ- Place the 3rd sticker on a paper that matches each sample in the LabPak you packaged. This will become your packing list for that LabPak. *1 paper per LabPak-If you have more than 1 LabPak of samples we need a separate sticker packing list for each LabPak*
- Make sure the date is on the sticker packing list paper along with the total number of samples in that LabPak and the LabPak number you are placing those samples in as well as your initials to verify everything is in order. Make a copy for your records and place this packing list inside the LabPak it matches.
(1 paper per LabPak-If you have more than 1 LabPak of samples we need a separate sticker packing list for each LabPak)
- Place the main shipping label on outside of box, set aside the bottom smaller label with the corresponding tracking# (see 3.Clinic Records and Tracking)

3. Clinic Records and Tracking

- PAPER REQ- Bundle the PINK copies together that match the shipping bag for your records. Place the corresponding LabPak number on that bundle of pink copies.
- EREQ clients- you will use your copy of the label packing list as your records of shipment
- Verify the packing list matches the LabPak number and the quantity of samples in the LabPak. Place the small label with tracking# on your copy of the sticker packing list. Retain for your records.
- This paperwork will provide the documentation needed in case a shipping bag is missing, or if the lab does not have record of receiving sample.

If there are missing samples or a missing LabPak, you can now find out which samples were in the LabPak and hopefully be able to track that particular LabPak down.

THE MISSION is to get each sample to the lab and each result back to the provider as quickly as possible without causing more than necessary work on any one part of the "FIELD to LAB back to FIELD" process. It is all about the patient and the important information that urine sample holds for the provider.

Sigma Health Services	Policy No.: P-4 Page 1 of 2
Subject: Competencies	Effective Date: 2/1/09
	Revised Date: 10/1/09

Policy

Sigma Health Services staff are competent to perform their job duties.

Procedures

1. Qualified professionals, associate professionals and paraprofessionals, as defined in DMH/DD/SAS rule 10 NCAC 27G .0104, demonstrate knowledge, skills and abilities required by the population served.
 - a. Knowledge – education or competency based training and knowledge of the specific population to be served.
 - b. Skills – developed set of practices to apply to specific population to be served.
 - c. Abilities – application of knowledge and skills to achieve desired outcomes for the specific population to be served.

2. An staff's knowledge, skills and abilities required by the population and service or support are:
 - a. verified by transcripts from college or other academic institutions, certificates, licensed or other documentation of training upon hiring and as changes occur;
 - b. verified through employment references and personal interviews;
 - c. enhanced through ongoing training and supervision;
 - d. evaluated following training post-tests, observations and input from stakeholder and individuals receiving services or supports; and
 - e. monitored through supervision.

3. Competencies are demonstrated by exhibiting core skills including:
 - a. technical knowledge;
 - b. cultural awareness;
 - c. analytical skills;
 - d. decision-making;
 - e. interpersonal skills;
 - f. communication skills; and
 - g. clinical skills.

4. Sigma Health Services may accept documentation from another organization or agency verifying a new staff's competencies when Sigma Health Services has determined that the organization or agency has an established training program and QI system that monitors competencies as required by rules and regulations.

Sigma Health Services	Policy No.: P-4 Page 2 of 2
Subject: Competencies	Effective Date: 2/1/09
	Revised Date: 10/1/09

5. Staff's knowledge and competencies are assessed regularly during supervision and formally during their annual performance evaluation. The performance evaluation is based on the job functions and competencies identified and conducted in collaboration with the direct supervisor with input from the staff being evaluated. The staff and supervisor sign the evaluation. If the staff refuses to sign the evaluation, the supervisor notes such on the form and reasons for not signing as indicated by the staff.
6. The performance evaluation is used to assess the staff's performance related to objectives established in the last evaluation period and establish measurable performance objective for the next year.
7. Qualified professionals as specified in 10A NCAC 27G .0104(18) (a) are deemed to have met the requirements of the competency-based employment system in the State Plan for MH/DD/SAS.
8. There are no "privileging" requirements for qualified professionals, associate professionals and paraprofessionals.

(Sigma Health Services assures compliance with all DMH/DD/SAS competencies at such time they are established.)