


 <p><b>Children's Hospital of Chicago Medical Center</b></p>	 <p><b>Children's Hospital of Chicago Medical Center</b></p>	 <p><b>Ann &amp; Robert H. Lurie Children's Hospital of Chicago, LLC</b> Chicago, IL 60611 Consent to Deliver Patient-Specific Prescription Drugs to Licensed Medical Practitioner</p>	 <p>Medical Record Number Patient Name Physician Referring Physician</p> <p><i>Please place patient label to the right</i></p>
<p><b>Standard Operating Procedure</b></p>	<p><b>Standard Operating Procedure</b></p>	<p><b>STANDARD OPERATING PROCEDURE</b></p>	
<p>Procedures for obtaining specially compounded Amino Acids from Integrity Compounding Pharmacy</p> <p>Scope: Pharmacy</p> <p>Effective Date: 7/29/19</p> <p>Page 1 of 2</p>	<p>Procedures for obtaining specially compounded Amino Acids from Integrity Compounding Pharmacy</p> <p>Scope: Pharmacy</p> <p>Effective Date: 7/29/19</p> <p>Page 2 of 2</p>	<p>Procedures for obtaining specially compounded Amino Acids from Integrity Compounding Pharmacy</p> <p>Scope: Pharmacy</p> <p>Effective Date: 7/29/19</p> <p>Page 2 of 2</p>	
<p><b>I. Purpose</b></p> <p>To outline the process for the procurement and ordering of specially compounded amino acid solutions obtained from an external pharmacy for upstart use in patients with inborn errors of metabolism.</p>	<p><b>II. Definitions</b></p> <p><b>Compounding:</b> the preparation, mixing, assembling, altering, packaging, and labeling of a new, one-time delivery device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioners' patient/ pharmacist-compound relationship in the course of professional practice.</p> <p><b>Compounding pharmacy:</b> a pharmacy that has made an investment in equipment and training to safely compound medications. These are classified as 503A (patient-specific compounds) and 503B (bulk compounding) pharmacies.</p> <p><b>Inborn Errors of Metabolism:</b> rare genetic disorders in the body cannot appropriate metabolites and/or produce metabolites. Examples include phenylketonuria (PKU), maple syrup urine disease (MSUD), and methylmalonic acidemia (MMA).</p> <p><b>Licensed Independent Practitioner (LIP):</b> An individual permitted by law and by the organization to provide care, treatment, and services without direct supervision. A licensed independent practitioner operates within the scope of his or her license, consistent with individually granted clinical privileges.</p>	<p><b>APPENDIX A: Consent to Deliver Patient-Specific Prescription Drugs to Licensed Medical Practitioner</b></p> <p>In accordance with GA Rule 480-16-02(3), which reads "In order for a patient to authorize a licensed medical practitioner to hold, administer, or deliver the patient's prescription drug at his or her office location, the drug was previously diagnosed and delivered to the practitioner's office by a pharmacy, the patient must first provide the pharmacy with written authority to conduct such a delivery." I hereby consent to allowing integrity compounding pharmacy (the "Pharmacy") to deliver any prescription drugs to my licensed medical practitioner. This consent will apply to all prescriptions dispensed by the Pharmacy for my child's medical condition, unless written at 5601 Dunwoody Place, Suite 700, Sandy Springs, GA 30350.</p> <p>I understand that I have the right to decline this method of delivery and I have voluntarily assumed the risk of this delivery. I hereby release, discharge, indemnify, hold harmless, and covenant not to sue the Pharmacy, its Board and against any and all claims, actions, damages, liabilities, losses, costs and expenses of any kind (including but not limited to reasonable attorneys' fees) arising out of or in connection with the shipment or delivery of any prescription drugs. I understand that the Pharmacy has not assumed any responsibility for or made any representations as to the handling of the product once in transit or by any third-party courier.</p>	
<p><b>III. Policy Statement</b></p> <p>A. A prescription is required to obtain specially compounded amino acid solutions from Integrity Pharmacy.</p> <p>B. Integrity pharmacy can ship same-day for crisis situations. Currently, these products are available for 72 hours. After December 1, 2019, the product is available for 96 hours after being compounded.</p> <p>C. A LIP from the Genetics team must order specially compounded amino acid solutions.</p> <p>D. The patient or patient's representative must sign a consent form to authorize delivery of solutions to the inpatient pharmacy.</p>	<p><b>IV. Procedures</b></p> <p>A. Call Integrity pharmacy to notify them of potential need:</p> <ol style="list-style-type: none"> <li>Business hours (04:45 pm to 5:30 pm) 404-813-1810</li> <li>Off-Hours</li> <li>Call Casey Gertson: 678-571-2853</li> <li>If Casey Gertson is unavailable, call the regular pharmacy to activate the on-call system: 404-813-1810</li> </ol> <p>B. The patient or the patient's representative must sign the consent form to authorize delivery of medication to the inpatient pharmacy (Appendix A) Representative of the integrity Pharmacy are willing to act as the patient's representative over the phone but may require facilitation by this discretion by the onsite Genetics Team.</p> <ol style="list-style-type: none"> <li>Consent form should be sent by the Genetics LIP or HMD to be scanned into the patient's chart. The paper copy can also be delivered to the Clinical Pharmacy Director who will deliver the form to HIM.</li> <li>A LIP from the Genetics Team must complete the Custom Amino Acid T1 Registration Form (Appendix B) and fax the form to 404-813-1609</li> <li>Integrity will review the Custom Amino Acid T1 Registration Form for appropriateness and fax back a completed ID coordination form.</li> <li>Integrity will coordinate delivery by an undelivered LIP or faxed back to Integrity.</li> <li>Emergency will coordinate delivery of supply to the inpatient pharmacy.</li> </ol> <p>F. The pharmacist should place an order in EPIC under the orderable "TPC, Integrity prepared solution" to the administration can be charted in the electronic medical record.</p> <p>G. The Pharmacy Clinical Director or designee will coordinate duration of therapy with Integrity.</p>		
<p>Date Written: 6/1/2019</p> <p>Date Reviewed/Revised: 6/18/2019; 7/29/2019</p> <p>Approved by: Anne Chakravarty, Senior Director, Pharmacy Services</p>			
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