

Fagron Sterile Services Statement of Clinical Difference

Fagron Sterile Services (“FSS”) compounds drug products pursuant to Section 503B of the Federal Food, Drug and Cosmetic Act. As such, pursuant to Section 503B(a)(5) of the Act and current FDA Guidance for Industry interpreting this provision, a statement of clinical difference made or approved by the practitioner who will prescribe and/or order the administration of the drug product (hereinafter collectively “prescribing practitioner”) must accompany each product order.

By signing this document, the signatory hereby attests that he/she is the prescribing practitioner who makes or approves of this statement of clinical difference. Additionally, by signing this document, the signatory hereby attests that the compounded preparation to which this statement of clinical difference applies will only be administered to patients for whom the prescribing practitioner determines will produce a clinical difference from the comparable approved drug product, as described more fully in the applicable statement of clinical difference below.

By signing this document, the signatory hereby attests only to the specific preparation(s) that have been ordered or otherwise obtained from FSS by the signatory (and/or the facility/facilities represented by or affiliated with the signatory). The signatory (and the facility/facilities represented by or affiliated with the signatory, if any) does not take a position or otherwise attest in any way to preparation(s) that have not been ordered or otherwise obtained from FSS.

Prep Type Code Descriptions Used on List of Preparations:

- 1 Prepared through Sterile Repack of commercially available products.
- 2 Prepared through In-Process Sterilization of active pharmaceutical ingredients (API).
- 3 Prepared through dilution, or reconstitution followed by dilution, of a sterile-manufactured product, or through in-process sterilization of manufactured products.

Product Category	Item	NDC	Prep Type	Item Description	Statement of Clinical Difference
Critical Care	2001399	71266-9091-01	2	Lidocaine HCl 2% (20mg/mL) Solution for Injection PF, 50mL Fill in 50mL Vial	Shortage specific. No Attestation.
Critical Care	2001101	71266-5030-01	2	Midazolam 1mg/mL (100mg/100mL) 100mL fill in a 100mL IV Bag	In my professional judgement: the use of the compounded Midazolam HCl Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use flexible plastic containers provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient sedation.

Critical Care	2001135	71266-5030-02	2	Midazolam 1mg/mL (50mg/50mL) 50mL fill in 100mL IV Bag	In my professional judgement: the use of the compounded Midazolam HCl Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use flexible plastic containers provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient sedation.
Critical Care	2001063	71266-9190-06	2	Midazolam 1mg/mL 50 mL Fill, 50 mL Syringe	In my professional judgement: the use of the compounded Midazolam HCl Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use infusion syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient sedation.
Critical Care	2001361	71266-9022-01	2	Phenylephrine 0.1mg/mL Solution, 50mL syringe	In my professional judgement: the use of the compounded Phenylephrine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials and ampules for patients who require these formulations during surgery or other medical procedures.
Critical Care	2001278	71266-5170-01	2	Phenylephrine HCl 200mg in 250mL 0.9% NaCl Bag (200mg/250mL)	In my professional judgement: the use of the compounded Phenylephrine HCl Solution that is compatible with our specialized drug administration equipment and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations.
Critical Care	2002617	71266-5230-01	2	Phenylephrine HCl 25mg added to 250mL 0.9% NaCl IV Bag (25mg/250mL)	In my professional judgement: the use of the compounded Phenylephrine HCl Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use Flexible Plastic Container provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations.

Critical Care	2002522	71266-5250-01	2	Phenylephrine HCl 50mg added to 250mL 0.9% NaCl IV Bag (50mg/250mL)	In my professional judgement: the use of the compounded Phenylephrine HCl Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use Flexible Plastic Container provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations.
Labor & Delivery	2001435	71266-9225-01	2	Fentanyl Citrate 2mcg/mL and Bupivacaine HCl 0.0625%, PF, 250mL Fill in 250mL IV Bag	In my professional judgement: the use of the compounded Fentanyl Citrate and Bupivacaine HCl Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use flexible plastic container provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Labor & Delivery	2001438	71266-9228-01	2	Fentanyl Citrate 2mcg/mL and Bupivacaine HCl 0.125%, PF, 100mL Fill in 100mL IV Bag	In my professional judgement: the use of the compounded Fentanyl Citrate and Bupivacaine HCl Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use flexible plastic container provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Labor & Delivery	2001437	71266-9227-01	2	Fentanyl Citrate 2mcg/mL and Bupivacaine HCl 0.125%, PF, 250mL Fill in 250mL IV Bag	In my professional judgement: the use of the compounded Fentanyl Citrate and Bupivacaine HCl Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use flexible plastic container provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.

Labor & Delivery	2001349	71266-9235-01	2	Fentanyl Citrate 2mcg/mL and Ropivacaine HCl 0.15% (1.5mg/mL), PF, 50mL Fill in 50mL Syringe	In my professional judgement: the use of the compounded Fentanyl Citrate and Ropivacaine HCl Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use PCA/infusion syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Labor & Delivery	2002597	71266-5103-01	2	Oxytocin 30 Units, Injection Solution, added to 500mL 0.9% NaCl FK Freeflex IV Bag	In my professional judgement: the use of the compounded Oxytocin Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use Flexible Plastic Containers provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations.
Labor & Delivery	2001097	71266-5000-01	3	Oxytocin 30 units, Injection Solution, added to 500mL 0.9% NaCl IV Bag Commercial Dilution	In my professional judgement: the use of the compounded Oxytocin Injection Solution that is compatible with our specialized drug administration equipment and packaged in labeled, ready-to-use flexible plastic containers provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations.
Ophthalmics	2001096	71266-8006-01	1	Avastin (Bevacizumab) Solution for Injection, 1.25mg/0.05mL. 0.12mL Fill CZ	In my professional judgement: the use of Avastin that is prepared via sterile transfer from commercially available drug solution and packaged in single-use, labeled, ready-to-use syringe provides clinical and safety benefits relative to comparable manufactured drug containers.
Ophthalmics	2000073	71266-8120-01	2	Epinephrine 1:1000 (1mg/mL), Injection Solution, Preservative Free/Sulfite Free, 1 mL fill in a 3mL Single-Use Syringe	Compared to comparable commercially available drug products, this compounded Epinephrine injection solution is free of the following ingredients: Sodium Metabisulfite, Sodium Bisulfite, Sodium Hydroxide, Chlorobutanol, and Disodium Edetate (dihydrate); in my professional judgement, this compounded product that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits to patients who require this formulation.

Ophthalmics	2000066	71266-6360-01	2	Lidocaine 1%/Phenylephrine 1.5% BSS Preservative Free /Sulfite Free Injection Solution 1 mL Single Use Syringe	This compounded Lidocaine and Phenylephrine injection solution is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Ophthalmics	2001389	71266-8475-03	2	mitoMYcin 0.02% (0.2 mg/mL) Ophthalmic Injection Solution, 1 mL fill in a 3 mL Single-Use Syringe	This compounded Mitomycin injection solution is different in route of administration, dosage form, dosage strength, and excipients compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Ophthalmics	2001390	71266-8515-03	2	mitoMYcin 0.04% (0.4 mg/mL) Ophthalmic Injection Solution, 1 mL fill in a 3 mL Single-Use Syringe	This compounded Mitomycin injection solution is different in route of administration, dosage form, dosage strength, and excipients compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Ophthalmics	2000096	71266-8613-01	3	moxifloxacin HCl (Avelox®) 0.1% (1 mg/mL) Ophthalmic Injection Solution, 0.3 mL in a 1 mL Single-Use Syringe	Compared to comparable commercially available drug products, this compounded Moxifloxacin ophthalmic injection solution is different in route of administration and dosage strength; in my professional judgement, this compounded product that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits to patients who require this formulation.
Ophthalmics	2000723	71266-8604-01	1	moxifloxacin HCl (generic for Avelox®) 0.16% (1.6 mg/mL) Oph Injection Sol, 1 mL in 3 mL Single-Use Syringe	In my professional judgement: the use of moxifloxacin that is prepared via sterile transfer from commercially available drug solution and packaged in single-use, labeled, ready-to-use syringe provides clinical and safety benefits relative to comparable manufactured drug containers.
Ophthalmics	2000083	71266-8241-05	2	tropicamide 1% / cyclopentolate 1% / PHENYLEphrine 10% / ketorolac 0.5% Topical Ophth Soln, 5 mL Multiple-Dose DB	This compounded Tropicamide 1%, Cyclopentolate 1%, Phenylephrine 10%, and Ketorolac 0.5% ophthalmic solution is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.

Ophthalmics	2000084	71266-8241-01	2	tropicamide 1% / cyclopentolate 1% / PHENYLEphrine 10% / ketorolac 0.5% Topical Ophthalmic Soln, 0.5 mL Single-Use Syr	This compounded Tropicamide 1%, Cyclopentolate 1%, Phenylephrine 10%, and Ketorolac 0.5% ophthalmic solution is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Ophthalmics	2000079	71266-8221-01	2	tropicamide 1% / cyclopentolate 1% / PHENYLEphrine 2.5% / ketorolac 0.4% / proparacaine 0.1%, Top Oph Soln, 0.5 mL Syr	This compounded Tropicamide 1%, Cyclopentolate 1%, Phenylephrine 2.5%, Ketorolac 0.4%, and Proparacaine 0.1% ophthalmic solution is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Ophthalmics	2000082	71266-8240-01	2	tropicamide 1% / cyclopentolate 1% / PHENYLEphrine 2.5% / ketorolac 0.5% Topical Ophth Soln, 0.5 mL Single-Use Syringe	This compounded Tropicamide 1%, Cyclopentolate 1%, Phenylephrine 2.5%, and Ketorolac 0.4% ophthalmic solution is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Ophthalmics	2000081	71266-8240-05	2	tropicamide 1% / cyclopentolate 1% / PHENYLEphrine 2.5% / ketorolac 0.5% Topical Ophthalmic Solution, 5 mL MDD Bottle	This compounded Tropicamide 1%, Cyclopentolate 1%, Phenylephrine 2.5%, and Ketorolac 0.4% ophthalmic solution is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Ophthalmics	2000077	71266-8211-01	2	tropicamide 1% / cyclopentolate 1% / PHENYLEphrine 2.5% Topical Ophthalmic Solution, 0.5 mL Single-Use Syringe	This compounded Tropicamide 1%, Cyclopentolate 1%, and Phenylephrine 2.5% ophthalmic solution is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.

Ophthalmics	2000076	71266-8211-05	2	tropicamide 1% / cyclopentolate 1% / PHENYLEphrine 2.5% Topical Ophthalmic Solution, 5 mL Multiple-Dose Dropper Bottle	This compounded Tropicamide 1%, Cyclopentolate 1%, and Phenylephrine 2.5% ophthalmic solution is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Ophthalmics	2001094	71266-8310-01	2	Tropicamide 1% / Phenylephrine 2.5% Ophthalmic Solution, 1mL fill in 3mL Dropper Bottle	This compounded Tropicamide 1% and Phenylephrine 2.5% ophthalmic solution is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
OR Syringes	2000636	71266-2010-01	1	Atropine sulfate 0.8mg per 2ml (0.4mg per mL), Injection Solution in a 3mL Syringe	In my professional judgement: the use of atropine sulfate that is prepared via sterile transfer from commercially available drug solution and packaged in single-use, labeled, ready-to-use syringe provides clinical and safety benefits relative to comparable manufactured drug containers.
OR Syringes	2002606	71266-9045-05	3	ePHEDrine sulfate 50mg/5mL (10mg/mL) IV Injection Solution in a 5mL Single-Use Syringe (Commercial Dilution)	In my professional judgement, the use of compounded Ephedrine Sulfate solution that is prepared and diluted from commercially available concentrated solution and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2001327	71266-9027-01	1	Ephedrine Sulfate 5mg/mL (25mg/5mL) 5mL in 5mL Syringe	Compared to comparable commercially available drug products, this Ephedrine Sulfate solution that is prepared via sterile transfer from commercially available drug solution and packaged in single-use, labeled, ready-to-use syringe provides clinical and safety benefits relative to comparable syringes provides clinical and safety benefits to patients who require this formulation.
OR Syringes	2000902	71266-9180-01	2	Fentanyl 10mcg/mL, 1mL fill in 3mL syringe	In my professional judgement: the use of the compounded Fentanyl Citrate Injection Solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials or ampules for patients who require these formulations for in-patient pain control.

OR Syringes	2000292	71266-9015-03	1	Glycopyrrolate 0.2mg/mL, 0.6mg per 3mL	In my professional judgement: the use of glycopyrrolate that is prepared via sterile transfer from commercially available drug solution and packaged in single-use, labeled, ready-to-use syringe provides clinical and safety benefits relative to comparable manufactured drug containers.
OR Syringes	2000291	71266-9015-05	1	Glycopyrrolate 0.2mg/mL, 1mg per 5mL	In my professional judgement: the use of glycopyrrolate that is prepared via sterile transfer from commercially available drug solution and packaged in single-use, labeled, ready-to-use syringe provides clinical and safety benefits relative to comparable manufactured drug containers.
OR Syringes	2000826	71266-9070-02	2	ketamine HCl 50 mg per mL 1mL Fill in 3mL Syringe Injection Solution	In my professional judgement: the use of the compounded Ketamine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2002670	71266-9080-03	2	ketamine HCl Injection 20 mg/2 mL (10 mg/mL) in a 3 mL Syringe	In my professional judgement: the use of the compounded Ketamine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2002671	71266-9080-04	2	ketamine HCl Injection 50 mg/5 mL (10 mg/mL) in a 5 mL Syringe	In my professional judgement: the use of the compounded Ketamine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000851	71266-9100-03	2	Lidocaine HCl 1% 10mg/mL Sol for Inj PF 10mL in 10mL syr	In my professional judgement: the use of the compounded Lidocaine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.

OR Syringes	2000850	71266-9090-01	2	lidocaine HCl 2% (20mg/mL) (100mg/5mL) Injection Solution PF 5mL in 5mL Syringe	In my professional judgement: the use of the compounded Lidocaine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000432	71266-2003-01	2	neostigmine methylsulfate 3 mg/3 mL (1 mg/mL) IV Injection Solution in a 5 mL Single-Use Syringe	In my professional judgement: the use of the compounded Neostigmine Methylsulfate solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000435	71266-2003-02	2	neostigmine methylsulfate 5 mg/5 mL (1 mg/mL) IV Injection Solution in a 5 mL Single-Use Syringe	In my professional judgement: the use of the compounded Neostigmine Methylsulfate solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000607	71266-9032-01	2	PHENYLEphrine 0.04mg/mL PF Inj Soln 10mL Syringe	In my professional judgement: the use of the compounded Phenylephrine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials and ampules for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000597	71266-9031-01	3	PHENYLEphrine HCL 0.4 mg per 10 mL (40 mcg per mL) Injection Solution in 10 mL Single-Use Syringe	In my professional judgement: the use of the compounded Phenylephrine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000599	71266-9010-02	3	PHENYLEphrine HCl 0.5 mg per 5 mL (100 mcg per mL) Injection Solution in a 5 mL Single-Use Syringe	In my professional judgement: the use of the compounded Phenylephrine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.

OR Syringes	2000601	71266-9030-01	3	PHENYLEphrine HCl 0.8 mg/10 mL (0.08 mg/mL) Injection Solution in a 10mL Single-Use Syringe	In my professional judgement: the use of compounded Phenylephrine solution that is prepared and diluted from commercially available concentrated solution and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000290	71266-9010-01	3	PHENYLEphrine HCl 100mcg per mL (1mg per 10mL) in 10mL Syringe Injection Solution (Sterile to Sterile Dilution)	In my professional judgement: the use of compounded Phenylephrine solution that is prepared and diluted from commercially available concentrated solution and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000598	71266-9011-01	2	PHENYLEphrine HCl 100mcg per mL (1mg per 10mL) in 10mL Syringe Injection Solution Preservative Free	In my professional judgement: the use of the compounded Phenylephrine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials and ampules for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2002605	71266-9035-09	3	RFID ePHEDrine sulfate 50mg/5mL (10mg/mL) IV Injection Solution in a 5mL Single-Use Syringe (Commercial Dilution)	In my professional judgement, the use of compounded Ephedrine Sulfate solution that is prepared and diluted from commercially available concentrated solution and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2001300	71266-2004-09	1	RFID glycopyrrolate 1 mg/5 mL (0.2 mg/mL) IV Injection Solution in a 5 mL Single-Use Syringe	In my professional judgement: the use of the compounded Glycopyrrolate solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2001303	71266-9090-09	2	RFID lidocaine HCl 2% (20mg/mL) (100mg/5mL) Injection Solution PF 5mL in 5mL Syringe	In my professional judgement: the use of the compounded Lidocaine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.

OR Syringes	2001299	71266-2003-09	2	RFID neostigmine methylsulfate 5 mg/5 mL (1 mg/mL) IV Injection Solution in a 5 mL Single-Use Syringe	In my professional judgement: the use of the compounded Neostigmine Methylsulfate solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2001294	71266-9010-09	3	RFID PHENYLEphrine HCl 100mcg per mL (1mg per 10mL) in 10mL Syringe Injection Solution (Sterile to Sterile Dilution)	In my professional judgement: the use of compounded Phenylephrine solution that is prepared and diluted from commercially available concentrated solution and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2001302	71266-9011-09	2	RFID PHENYLEphrine HCl 100mcg per mL (1mg per 10mL) in 10mL Syringe Injection Solution Preservative Free	In my professional judgement: the use of the compounded Phenylephrine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials and ampules for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2001298	71266-2002-09	2	RFID rocuronium bromide 50 mg/5 mL (10 mg/mL) IV Injection Solution in a 5 mL Single-Use Syringe	In my professional judgement: the use of the compounded Rocuronium Bromide injection solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2001296	71266-2001-09	2	RFID succinylcholine chloride 100 mg/5 mL (20 mg/mL) IV Injection Solution in a 10 mL Single-Use Syringe	In my professional judgement: the use of the compounded Succinylcholine Chloride solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2001297	71266-2001-08	2	RFID succinylcholine chloride 200 mg/10 mL (20 mg/mL) IV Injection Solution in a 10 mL Single-Use Syringe	In my professional judgement: the use of the compounded Succinylcholine Chloride solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.

OR Syringes	2000289	71266-9005-05	1	rocuronium bromide 50 mg/5 mL (10 mg/mL) IV Injection Solution in a 5 mL Single-Use Syringe	In my professional judgement: the use of rocuronium bromide that is prepared via sterile transfer from commercially available drug solution and packaged in single-use, labeled, ready-to-use syringe provides clinical and safety benefits relative to comparable manufactured drug containers.
OR Syringes	2000433	71266-2002-01	2	rocuronium bromide 50 mg/5 mL (10 mg/mL) IV Injection Solution in a 5 mL Single-Use Syringe	In my professional judgement: the use of the compounded Rocuronium Bromide injection solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000305	71266-9684-05	1	succinylcholine chloride 100 mg/5 mL (20 mg/mL) IV Injection Solution in a 5 mL Single-Use Syringe	In my professional judgement: the use of succinylcholine chloride that is prepared via sterile transfer from commercially available drug solution and packaged in single-use, labeled, ready-to-use syringe provides clinical and safety benefits relative to comparable manufactured drug containers.
OR Syringes	2000423	71266-2001-01	2	succinylcholine chloride 100 mg/5 mL (20 mg/mL) IV Injection Solution in a 10 mL Single-Use Syringe	In my professional judgement: the use of the compounded Succinylcholine Chloride solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000508	71266-2001-03	2	succinylcholine chloride 140 mg/7 mL (20 mg/mL) IV Injection Solution in a 10 mL Single-Use Syringe	In my professional judgement: the use of the compounded Succinylcholine Chloride solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
OR Syringes	2000431	71266-2001-02	2	succinylcholine chloride 200 mg/10 mL (20 mg/mL) IV Injection Solution in a 10 mL Single-Use Syringe	In my professional judgement: the use of the compounded Succinylcholine Chloride solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.

Pain Management	2000794	71266-9160-02	2	Bupivacaine HCl Injection 0.25% (2.5mg/mL) 10mL Fill	In my professional judgement: the use of the compounded Bupivacaine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
Pain Management	2001065	71266-9170-05	2	Fentanyl 50mcg/mL 30mL fill, 30 mL syringe	In my professional judgement: the use of the compounded Fentanyl Citrate Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use PCA/infusion syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Pain Management	2001066	71266-9170-06	2	Fentanyl 50mcg/mL 50 mL fill, 50 mL syringe	In my professional judgement: the use of the compounded Fentanyl Citrate Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use PCA/infusion syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Pain Management	2001125	71266-5050-01	2	Fentanyl Citrate 10mcg/mL (1000mcg/100mL) 100mL fill in a 100mL IV Bag	In my professional judgement: the use of the compounded Fentanyl Citrate Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use Flexible Plastic Container provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Pain Management	2001099	71266-5010-01	2	Fentanyl Citrate 10mcg/mL (2,500mcg/250mL) 250mL fill in a 250mL IV Bag	In my professional judgement: the use of the compounded Fentanyl Citrate Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use Flexible Plastic Container provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.

Pain Management	2001124	71266-5040-01	2	Fentanyl Citrate 20mcg/mL (2,000mcg/100mL) 100mL fill in a 100mL IV Bag	In my professional judgement: the use of the compounded Fentanyl Citrate Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use Flexible Plastic Container provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Pain Management	2001098	71266-5005-01	2	Fentanyl Citrate 50mcg/mL (2500mcg/50mL) 50mL fill in 100mL IV Bag	In my professional judgement: the use of the compounded Fentanyl Citrate Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use Flexible Plastic Container provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Pain Management	2001100	71266-5035-01	2	Hydromorphone HCL 0.2 mg/mL (20mg/100mL) 100mL fill in a 100mL IV Bag	In my professional judgement: the use of the compounded Hydromorphone HCL Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use flexible plastic containers provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Pain Management	2001053	71266-9110-04	2	Hydromorphone HCL 0.2mg/mL 30mL Fill, 30mL Syringe	In my professional judgement: the use of the compounded Hydromorphone HCL Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use PCA/infusion syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.

Pain Management	2001054	71266-9110-03	2	Hydromorphone HCl 0.2mg/mL 50mL Fill, 50mL Syringe	In my professional judgement: the use of the compounded Hydromorphone HCl Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use PCA/infusion syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Pain Management	2001055	71266-9115-01	2	Hydromorphone HCl 1mg/mL 30mL Fill, 30mL Syringe	In my professional judgement: the use of the compounded Hydromorphone HCl Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use PCA/infusion syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Pain Management	2001192	71266-5055-02	2	Hydromorphone HCl 1mg/mL 50mL Fill, 100mL IV Bag	In my professional judgement: the use of the compounded Hydromorphone HCl Injection Solution that is in-process sterilized, compatible with our specialized drug administration equipment, and packaged in labeled, ready-to-use flexible plastic containers provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations for in-patient pain control.
Pain Management	2001218	71266-9081-01	2	Ketamine HCl 1000mg/100mL (10mg/mL) in 100mL IV Bag	In my professional judgement: the use of the compounded Ketamine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use bags provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
Pain Management	2000065	71266-6519-01	2	Phenol in Water Injection Solution, 6%, 10-mL Multiple- Dose Vial	This compounded Phenol injection solution is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.

Pain Management	2000825	71266-9130-01	2	Ropivacaine 0.50% 20mL fill in 20mL Syringe	In my professional judgement: the use of the compounded Ropivacaine HCl solution that is in-process sterilized and packaged in labeled, ready-to-use syringes provides clinical and safety benefits relative to comparable manufactured drug vials for patients who require these formulations during surgery or other medical procedures.
Specialty	2001258	71266-8020-01	2	AminoProtect (L-Lysine HCl 2.5%, L-Arginine HCl 2.5%) 1000ml IV Bag	In my professional judgement: the use of compounded AminoProtect preparation that has one or more variations in: active ingredient(s), route of administration, dosage form, dosage strength, and excipient(s) from comparable manufactured drug products provides clinical and safety benefits for patients who require these formulations.
Specialty	2001089	72682-2726-03	2	Ascorbic Acid (PF-Non Corn) Injection	In my professional judgement, the use of this product is clinically necessary for patients who have reactions or sensitivity to Ascorbic Acid that is synthetic or sourced from corn similar to the commercially available product.
Specialty	2000051	71266-1025-01	2	BETAmethasone sodium phosphate 6 mg/mL, Injection Solution, Preservative Free, 1 mL Single-Dose Vial	This compounded Betamethasone Sodium Phosphate injection solution is free of the active ingredient Betamethasone Acetate and free of the preservative Benzalkonium Chloride compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation, including patients who are sensitive or allergic to Benzalkonium Chloride.
Specialty	2000052	71266-1025-02	2	BETAmethasone sodium phosphate 6 mg/mL, Injection Solution, Preservative Free, 2 mL Single-Dose Vial	This compounded Betamethasone Sodium Phosphate injection solution is free of the active ingredient Betamethasone Acetate and free of the preservative Benzalkonium Chloride compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation, including patients who are sensitive or allergic to Benzalkonium Chloride.

Specialty	2000053	71266-1041-02	2	DEXAmethasone sodium phosphate 10 mg/mL, Injection Solution, Preservative Free, 2 mL Single-Dose Vial	This compounded Dexamethasone Sodium Phosphate injection solution is free of the preservative Benzalkonium Chloride compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation, including patients who are sensitive or allergic to Benzalkonium Chloride.
Specialty	2000054	71266-1051-02	2	DEXAmethasone sodium phosphate 4 mg/mL, Injection Solution, Preservative Free, 2 mL Single-Dose Vial	This compounded Dexamethasone Sodium Phosphate injection solution is free of the preservative Benzalkonium Chloride compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation, including patients who are sensitive or allergic to Benzalkonium Chloride.
Specialty	2000997	71266-6290-01	2	Lidocaine, Epinephrine, Tetracaine Gel 3ml Syringe (LET Gel) Sterile Topical Gel	This compounded Lidocaine and Epinephrine and Tetracaine topical gel is different in active ingredients and dosage strengths compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Specialty	2001388	71266-6412-03	2	mitoMYcin 20 mg/40 mL (0.5 mg/mL), Solution for Bladder Instillation, 2 x 40 mL Single-Use Syringes per Dose	This compounded Mitomycin Bladder Instillation irrigant is different in route of administration, dosage form, dosage strength, and excipients compared to comparable commercially available drug products; in my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Specialty	2000063	71266-6487-05	1	Omnipaque 240 mg/mL Injectable 5 mL Single-Use Vial	In my professional judgement: the use of Omnipaque that is prepared via sterile transfer from commercially available drug solution and packaged in single-use, labeled, ready-to-use vial provides clinical and safety benefits relative to comparable manufactured drug containers.
Specialty	2000064	71266-6488-03	1	Omnipaque 300 mg/mL Injectable 3 mL Single-Use Vial	In my professional judgement: the use of Omnipaque that is prepared via sterile transfer from commercially available drug solution and packaged in single-use, labeled, ready-to-use vial provides clinical and safety benefits relative to comparable manufactured drug containers.

Specialty	2000456	71266-6670-03	2	sodium citrate 4% containing GENTamicin 320 mcg/mL Injection Solution, 3 mL fill in a 5 mL Single-Use Syringe	This compounded Sodium Citrate and Gentamicin injection solution is different in active ingredients, dosage volume, and intended use compared to comparable commercially available drug products. The compounded presentation contains gentamicin antibiotic and benzyl alcohol preservative. In my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Specialty	2000458	71266-6670-04	2	sodium citrate 4% containing GENTamicin 320 mcg/mL Injection Solution, 5 mL fill in a 5 mL Single-Use Syringe	This compounded Sodium Citrate and Gentamicin injection solution is different in active ingredients, dosage volume, and intended use compared to comparable commercially available drug products. The compounded presentation contains gentamicin antibiotic and benzyl alcohol preservative. In my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Specialty	2000059	71266-6670-01	2	sodium citrate 4% containing GENTamicin 320mcg/mL Injection Solution 30mL Multiple-Dose Vial	This compounded Sodium Citrate and Gentamicin injection solution is different in active ingredients, dosage volume, and intended use compared to comparable commercially available drug products. The compounded presentation contains gentamicin antibiotic and benzyl alcohol preservative and is intended for multiple dose use. In my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.
Specialty	2000058	71266-6641-01	2	sodium CITrate 4% Injection Solution 30 mL Multiple-Dose Vial	This compounded Sodium Citrate injection solution is different in ingredients and dosage volume compared to comparable commercially available drug products. The compounded presentation contains benzyl alcohol preservative and is intended for multiple dose use. In my professional judgement, this compounded product provides clinical and safety benefits to patients who require this formulation.

Please complete and sign below as acknowledgment and confirmation of the applicable statement of clinical difference corresponding to the above preparations.

☐ **I'm signing this** statement of clinical difference on behalf of one facility, listed below.

☐ **I'm signing this** statement of clinical difference on behalf of multiple facilities, please reference attached list for facilities this statement of clinical difference covers. (List of facilities must be attached.)

Facility Name: _____

Name: _____

Title: _____

Signature: _____ Date: _____

Note:

Please return all pages (1-19) and list of facilities (if more than one) upon completion.