

Bausch & Lomb, Americas, Inc. 400 Somerset Corporate Blvd Bridgewater, New Jersey 08807 Tel: 908.927.1400

www.bausch.com

June 5, 2024

Dear 340B Covered Entities,

I am writing to inform you that Bausch & Lomb Americas Inc. ("Bausch & Lomb") is altering its approach to distributing products purchased at the 340B price. Effective July 1, 2024, Bausch & Lomb will ship products purchased at the 340B price exclusively to locations registered as a 340B covered entity or child site location affiliated with that covered entity.

To ensure all 340B covered entities can access Bausch & Lomb's products at the 340B price, any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location within 40 miles of the covered entity parent site. Bausch & Lomb is utilizing the 340B ESP™ platform to support this designation. 340B covered entities that do not have an in-house pharmacy and haven't already registered an account with 340B ESP™, can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab. Further details regarding this model can be found in the enclosed Frequently Asked Questions document. If you have questions regarding the change in our 340B distribution model, please contact us at support@340Besp.com.

Bausch & Lomb welcomes the voluntary submission of claims from covered entities in order to increase transparency and further the integrity and mission of the 340B program. Covered entities may continue to submit 340B claims through 340B ESP™ for all utilization dispensed through their contract pharmacies. Any covered entity that elects to submit its 340B claims, however, will not be eligible to continue Bill To / Ship To replenishment orders for each of its contract pharmacies but will be limited to the one designated contract pharmacy as set forth above. Covered entities that are interested in submitting 340B claims will need to register an account with 340B ESP™ and it is requested they submit the 340B claims on a pharmacy-by-pharmacy basis within 45 days of the dispense date.

In support of a smooth transition to our new distribution model, 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To replenishment orders in advance of the effective date of this notice. PHS contracts administered by our wholesalers will no longer support distribution of 340B purchased drugs to non-designated 340B contract pharmacies after June 30, 2024.

Best regards,

—Docusigned by: Yolandu Barnard

SVP & GM Ophthalmic Pharmaceuticals and Market Access

### **Frequently Asked Questions**

### Q. Which products are subject to Bausch & Lomb's policy?

A: Bausch & Lomb's contract pharmacy policy applies to all products set forth on the attached list.

# Q. My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to Bausch & Lomb's policy?

A: Any hospital covered entity may elect to designate a contract pharmacy location registered on the HRSA OPAIS database located within 40 miles of the covered entity parent site, regardless of ownership interest, as its single contract pharmacy location.

# Q. My covered entity has an in-house pharmacy that is capable of purchasing and dispensing Bausch & Lomb drugs, but my entity doesn't use it to dispense Bausch & Lomb drugs. Can my entity designate one contract pharmacy instead?

A: No, under Bausch & Lomb's policy, if a covered entity has an in-house pharmacy capable of dispensing 340B purchased products to eligible patients then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

# Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g. six different Accredo pharmacy locations). Can my entity designate all locations of the same pharmacy?

A. No. Bausch & Lomb's policy allows qualifying 340B covered entities (i.e., covered entities without an in-house pharmacy) to designate a single contract pharmacy location within 40 miles of the covered entity parent site. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

### Q. How often can my covered entity change its contract pharmacy designation?

A. Covered entities may change their contract pharmacy designation once every twelve (12) months (from the date of first designation) or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database.

#### Q. How does my covered entity change its contract pharmacy designation?

A. A 340B covered entity that has designated a single contract pharmacy in accordance with Bausch & Lomb's policy may change its contract pharmacy designation only after twelve (12) months following the original designation and then again after each successive twelve (12) months. If, however, a covered entity terminates its contract with the designated contract pharmacy <u>and</u> indicates such termination in the HRSA OPAIS database the covered entity may designate a new single contract pharmacy immediately following the effective date of the termination of the prior designated contract pharmacy. Changes to the single contract pharmacy can only be made by visiting www.340Besp.com/designations. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their contract pharmacy designation. Any other requests for a change in a designated contract pharmacy must be sent as an exception request to Bausch & Lomb for determination in its sole discretion.

# Q. Is Bausch & Lomb requiring covered entities to have a HIN registered for the contract pharmacy that they designate?

A. Yes, a contract pharmacy must have a HIN assigned to it in order for a covered entity to designate it as its single contract pharmacy. This information is important for Bausch & Lomb to manage its process with its wholesalers.

## Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?

A: Bausch & Lomb will not register a HIN on your behalf, however if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to support@340besp.com. If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions for how to obtain a HIN.

## Q. How does my covered entity ensure that its eligible contract pharmacy locations take effect on July 1, 2024?

A. For a covered entity's eligible contract pharmacy locations to take effect on July 1, 2024, the entity must designate by **June 23, 2024**. After July 1, 2024, please allow 10 business days for the eligible contract pharmacy locations to take effect.

## Q. How long does it take for my covered entity's eligible contract pharmacy locations to take effect after July 1, 2024?

A. Covered entities can take action to comply with Bausch & Lomb's policy after it goes into effect on July 1, 2024. After July 1, 2024, please allow 10 business days for the eligible contract pharmacy locations to take effect.

# Q. My covered entity would like to submit 340B claims for its contract pharmacies and continue purchasing Bausch & Lomb products at the 340B price. What does our entity need to do to begin submitting 340B claims?

A: 340B covered entities that wish to submit 340B claims from the single designated contract pharmacy under Bausch & Lomb's policy can do so by registering an account at www.340Besp.com. Users that have registered an account with 340B ESP™ can begin submitting 340B claims for Bausch & Lomb by navigating to the Claims Data Submission tab. 340B claims must be submitted within 45 days of the date of dispense in order for the contract pharmacy to remain eligible to receive 340B priced drugs.

### Q. My covered entity submitted 340B claims for a single contract pharmacy location. Will my entity now have access to all contract pharmacy locations?

A: No. While we encourage the submission of 340B claims through 340B ESP™, a covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may only designate a single contract pharmacy location within forty (40) miles of the covered entity parent site.

DESCRIPTION	UNIT SIZE
ALREX® (loteprednol etabonate ophthalmic suspension 0.2%)	5mL
ALREX® (loteprednol etabonate ophthalmic suspension 0.2%)	10mL
Atropine Sulfate Ophthalmic Solution, USP (1%) - Isopto Atropine Ophthalmic AG (generic)	10 x 0.4 ml
Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment, USP (generic)	3.5g
Bepotastine Besilate Ophthalmic Solution, 1.5% - Bepreve AG (generic)	5mL
Bepotastine Besilate Ophthalmic Solution, 1.5% - Bepreve AG (generic)	10mL
BEPREVE™ Ophthalmic Solution USP, 1.5%	5mL
BEPREVE™ Ophthalmic Solution USP, 1.5%	10mL
BESIVANCE® (besifloxacin ophthalmic suspension 0.6%)	5mL
Brimonidine Tartrate Ophthalmic Solution USP 0.2% (generic)	5mL
Brimonidine Tartrate Ophthalmic Solution USP 0.2% (generic)	10mL
Brimonidine Tartrate Ophthalmic Solution USP 0.2% (generic)	15mL
Brinzolamide Ophthalmic Suspension, USP 1% (generic)	10mL
Brinzolamide Ophthalmic Suspension, USP 1% (generic)	15mL
Bromfenac Ophthalmic Solution 0.07% (generic)	3mL
Cyclopentolate Hydrochloride Ophthalmic Solution USP, 1% (generic)	2mL
Cyclopentolate Hydrochloride Ophthalmic Solution USP, 1% (generic)	15mL
Dexamethasone Sodium Phosphate Ophthalmic Solution USP, (generic)	5mL
Diclofenac Sodium Ophthalmic Solution USP, 0.1% (generic)	5mL
Dorzolamide Hydrochloride Ophthalmic Solution USP, 2% (generic)	10mL
Dorzolamide Hydrochloride/Timolol Ophthalmic Solution USP, (generic)	10mL
Erythromycin Ophthalmic Ointment USP, 0.5% 50x1gm (generic)	50 x 1g
Erythromycin Ophthalmic Ointment USP, 0.5% (generic)	3.5g
FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE OPHTHALMIC SOLUTION 0.3%/0.4% (STERILE) 5mL	5mL
Gentamicin Sulfate Ophthalmic Solution USP, 0.3% (generic)	5mL
ISTALOL™ Ophthalmic Solution USP, 0.5%	2.5mL
ISTALOL™ Ophthalmic Solution USP, 0.5%	5mL
LACRISERT® (hydroxypropyl cellulose ophthalmic insert), 5mg	60
Latanoprost Ophthalmic Solution USP, 0.005% (generic)	2.5mL
Levobunolol Hydrochloride Ophthalmic Solution USP, 0.5% (generic)	5mL
LOTEMAX® (loteprednol etabonate ophthalmic Gel 0.5%)	5g
LOTEMAX® (loteprednol etabonate ophthalmic Ointment 0.5%)	3.5g
LOTEMAX® (loteprednol etabonate ophthalmic suspension 0.5%)	5mL
LOTEMAX® (loteprednol etabonate ophthalmic suspension 0.5%)	10mL
LOTEMAX® (loteprednol etabonate ophthalmic suspension 0.5%)	15mL
LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38%	5g
Loteprednol Etabonate Ophthalmic Gel 0.5%, 5g - Lotemax Gel AG (generic)	5g
Loteprednol Etabonate Ophthalmic Suspension 0.2%, 5mL - Alrex AG (generic)	5mL
LOTEPREDNOL ETABONATE OPHTHALMIC SUSPENSION 0.5%, 10mL - Lotemax AG	10mL
LOTEPREDNOL ETABONATE OPHTHALMIC SUSPENSION 0.5%, 15mL - Lotemax AG	15mL
LOTEPREDNOL ETABONATE OPHTHALMIC SUSPENSION 0.5%, 5mL - Lotemax AG	5mL
METHAZOLAMIDE TABLETS USP 25mg	100

DESCRIPTION	UNIT SIZE
METHAZOLAMIDE TABLETS USP 50mg	100
MIEBO™ ( Perfluorohexyloctane ophthalmic solution, 100%) 3mL	3mL
MIOCHOL®-E Intraocular Solution Reconstituted 20mg vial	1
Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment (generic)	3.5g
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment (generic)	3.5g
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension (generic)	5mL
Neomycin and Polymyxin B Sulfates and Gramicidin Ophthalmic Solution (generic)	10mL
Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution USP (generic)	10mL
Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension USP (generic)	10mL
Neomycin and Polymyxin B Sulfates, Bacitracin Zinc Hydrocortisone Acetate Ophthalmic Ointment (generic)	3.5mL
Ofloxacin Ophthalmic Solution, 0.3% (generic)	5mL
Ofloxacin Ophthalmic Solution, 0.3% (generic)	10mL
Ofloxacin Otic Solution, 0.3% (generic)	5mL
Ofloxacin Otic Solution, 0.3% (generic)	10mL
Phenylephrine Hydrochloride Ophthalmic Solution USP, 10% (generic)	5mL
Phenylephrine Hydrochloride Ophthalmic Solution USP, 10% (generic)	5mL
Phenylephrine Hydrochloride Ophthalmic Solution USP, 2.5% (generic)	10mL
Phenylephrine Hydrochloride Ophthalmic Solution USP, 2.5% (generic)	10mL
Prednisolone Sodium Phosphate Ophthalmic Solution USP, 1% (generic)	10mL
PROLENSA™ (bromfenac ophthalmic solution) 0.07% 3mL	3mL
Proparacaine Hydrochloride Ophthalmic Solution USP, 0.5% (generic)	15mL
Retisert (Floucinolone Acetonide Intravitreal implant)	1
Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution 10%/0.23% (generic)	5 mL
Sulfacetamide Sodium Ophthalmic Solution USP, 10% (generic)	15 mL
Tetracaine Hydrochloride Ophthalmic Solution, USP 0.5%, 15mL (OCEANSIDE)	15mL
Tetracaine Hydrochloride Ophthalmic Solution, USP 0.5%, 5mL (OCEANSIDE)	5mL
Timolol Maleate Ophthalmic Gel Forming Solution, 0.25% - Timoptic-XE AG (generic)	5mL
Timolol Maleate Ophthalmic Gel Forming Solution, 0.50% - Timoptic-XE AG(generic)	5mL
Timolol Maleate Ophthalmic Solution 0.5%, 2.5mL - Istalol AG (OCEANSIDE)	2.5mL
Timolol Maleate Ophthalmic Solution 0.5%, 5mL - Istalol AG (OCEANSIDE)	5mL
TIMOLOL MALEATE OPHTHALMIC SOLUTION 0.5%, 5mL - Timoptic AG	5mL
TIMOLOL MALEATE OPHTHALMIC SOLUTION 0.5%, 5mL - Timoptic AG (OCEANSIDE)	5mL
Timolol Maleate Ophthalmic Solution in OCUDOSE® 0.5% 0.3mL - Timoptic in OCUDOSE AG (generic)	60
TIMOPTIC® in OCUDOSE® (TIMOLOL MALEATE OPHTHALMIC SOLUTION) 0.25%, 0.3mL	60
TIMOPTIC® in OCUDOSE® (TIMOLOL MALEATE OPHTHALMIC SOLUTION) 0.50%, 0.3mL	60
Tobramycin and Dexamethasone Ophthalmic Suspension USP, 0.3%/0.1% (generic)	2.5mL
Tobramycin and Dexamethasone Ophthalmic Suspension USP, 0.3%/0.1% (generic)	5mL
Tobramycin and Dexamethasone Ophthalmic Suspension USP, 0.3%/0.1% (generic)	10mL
Tobramycin Ophthalmic Solution USP, 0.3% (generic)	5mL
Trimethoprim Sulfate and Polymyxin B Sulfate Ophthalmic Solution (generic)	10mL
Tropicamide Ophthalmic Solution, USP 0.5% (generic)	15mL
Tropicamide Ophthalmic Solution, USP 1% (generic)	2mL
Tropicamide Ophthalmic Solution, USP 1% (generic)	15mL

	UNIT
DESCRIPTION	SIZE
VISUDYNE® (verteporfin for injection) (Besse - sole specialty distributor)	vial
VYZULTA™ (latanoprostene bunod ophthalmic solution) 0.024%, 2.5mL	2.5mL
VYZULTA™ (latanoprostene bunod ophthalmic solution) 0.024%, 2.5mL	2.5mL
VYZULTA™ (latanoprostene bunod ophthalmic solution) 0.024%, 5mL	5mL
VYZULTA™ (latanoprostene bunod ophthalmic solution) 0.024%, 5mL	5mL
XIIDRA® (lifitegrast ophthalmic solution) 5%	5ea
XIPERE™ (triamcinolone acetonide injectable suspension) 40 mg/mL	40mg/mL
ZIRGAN™ (Ganciclovir Ophthalmic Gel 0.15%)	5mL
ZYLET® (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic Suspension)	5mL
ZYLET® (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic Suspension)	10mL

Note: Bausch and Lomb Americas Inc. reserves the right to add or remove products from this list.