

340B Matters

Wednesday, September 2, 2020

Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Recent Announcements from Major Pharmaceutical Companies Impacting Contract Pharmacy Participation in the 340B Program

Dear Secretary Azar,

We, the undersigned 340B Covered Entities, wish to express our most dire concerns around multiple, recent communications by Big Pharma detailing their proposed 340B Drug Discount Program “integrity initiative”. We acknowledge the Manufacturers’ stated desire to work collaboratively to strengthen the integrity of the 340B program. As evidenced by annual attestations by each Authorized Official at every participating 340B Covered Entity, our clear intent to work in accordance with all HRSA program directives and in good faith with manufacturers to avoid duplicate discounts in the Medicaid FFS population remains steadfast and transparent.

This Covered Entity collective wishes to communicate robust trepidation around both the nature and the timing of Big Pharma’s recent unseemly, aggressive, and opportunistic actions. The unauthorized Manufacturer program modification was initiated in early July 2020 in an attempt to forcibly affect possibly the most calculated and self-serving initiative seen in the history of the 340B program. It is not lost on this Covered Entity group that this dramatic aggression was launched during a period where already overwhelmed hospitals face dwindling supplies and manpower. Amidst unrivaled economic downturn, civil unrest, and a never seen before pandemic yielding mounting joblessness, extended sheltering in place and widespread food shortages, Big Pharma chose to exert its self-imposed authority over multiple facets of an existing and successful 340B program.

Under existing regulatory guidance, the 340B program has successfully supported the country’s uninsured and underinsured community since 1992. The unauthorized attacks and restrictions being launched by Manufacturers including Novartis, Merck, Lilly, and Astra Zeneca are direct threats to the very medications secured through the 340B program as well as the services and programs directly funded through the program’s savings, which provide care to the nation’s most vulnerable patient populations. As Covered Entities, we oppose several aspects of Big Pharma’s integrity initiative including the mandate that Covered Entities submit **ALL** claims for products secured through the 340B program into the Manufacturer’s chosen ESP platform. The aggressive demand for Covered Entities to

340B Matters

participate was not reinforced by any evidence of duplicate discounts but rather on what appears to be a broad assumption that duplicate discount payments are widespread. Section 340B (a)(5)(C) of the PHS Act allows manufacturers to audit Covered Entities to ensure compliance with duplicate discount prohibitions. Guidelines for these audits are listed in the Federal Register at 61 FR 65406 that HRSA published December 12, 1996. Inside those guidelines, it states that before conducting an audit the Manufacturer must submit audit work plans to HRSA for review. By demanding Covered Entities provide claims detail on a bi-weekly basis, Manufacturers are essentially requiring Entities to participate in an unsubstantiated, non-HRSA regulated, Entity funded perpetual manufacturer audit. Especially during these unprecedented times, surely it is clear hospitals and grantees lack the additional workforce required to indulge the Manufacturer's expanded, self-imposed accounting requirements. In essence, Manufacturers are asking Covered Entities to use already thinly stretched program benefits to assist them in achieving their own program auditing goals.

- 1) Under decades-old HIPAA regulations, Covered Entities have a legal duty to ensure protected patient health information is not inappropriately shared. In the FAQ section of the Manufacturer demand letters, they briefly detail the process for uploading **all-payer** claims into the 340B ESP platform. The Manufacturers mention that the platform will de-identify patient-specific data. Entities are understandably concerned about the security around this process which to our knowledge has been vetted only by the very Manufacturers it is being funded by. For Entities to upload any data containing patient information, it would be prudent and best practice to have in place a business associate's agreement with both the Manufacturer and the vendor *Second Sight Solutions*. In addition, System IT teams will need to establish that security protocols for the 340B ESP platform are adequate to prevent a HIPAA breach.
- 2) Contract Pharmacy Services agreements contain language addressing the sharing of information related to outside agencies. We are concerned that the ongoing sharing of claim information unrelated to 340B program requirements may result in a breach of these agreements, putting our 340B programs at undue risk. Multiple Contract Pharmacy partners have already begun communicating they do not support the sharing of claims information in the manner described by the Manufacturers.
- 3) Manufacturers claim they intend to use data provided by Covered Entities to "ensure it isn't paying duplicate Medicaid discounts and duplicate discounts on Medicare Part D and commercial utilization through our contracts with commercial payers." While we readily concur the Covered Entity has a duty to prevent duplicate discounts for Medicaid FFS claims, a process we are quite willing to work with Manufacturer to address, we do not agree that a Covered Entity has a corresponding duty to prevent discounts voluntarily paid by Manufacturer to Pharmacy Benefit Managers (PBMs) for drugs purchased under the 340B program. Payments of these discounts are not required as part of 340B and as such, there are no 340B integrity issues associated with them. Since payment of these discounts do not violate the 340B program, it can

340B Matters

only be assumed that the Manufacturer will use information gleaned from these claims to reduce payments to PBMs, worsening discriminatory contracting and reimbursement practices already occurring.

The above points represent rapidly escalating concern for this Entity group as certain Manufacturers have threatened to rescind 340B pricing should any requested data be withheld from them. One Manufacturer has gone as far as expressing they will not permit 340B pricing beyond one designated Contract Pharmacy location beginning October 1st, 2020. Such unauthorized acts of aggression will clearly cause a massive obstruction of programs that our Entities currently offer, ultimately hurting the most vulnerable patient populations these safety-net providers serve. These Entities respectfully ask your guidance as the stakes here are very high; current 340B hospitals and Entities are responsible for 60% of the nation's uncompensated and unreimbursed care which totals over \$26 billion.

Again, this group remains fully supportive of HRSA's authority and standing directive to Covered Entities to work with Manufacturers with respect to program integrity issues. Covered Entities in good faith engaged in the 340B Program as a *government*-directed program. As such, we respectfully ask that HRSA resume guidance and full enforcement of current rules and regulations within the program.

Given the concerns outlined above, the below signed feel we cannot comply with participation in the Manufacturer's proposed integrity program at this time. This collective would however, welcome the opportunity to meet with Manufacturers *and* yourself or your designee to discuss how we could, within the existing regulatory guidance of HRSA and the 340B program, strengthen 340B program integrity.

Most Respectfully,

**Advocates for a Healthy
Community**
Springfield, MO
Cliff Conquest

Carlinville Area Hospital
Carlinville, IL
Michael J. Brown (CFO)

Clay County Hospital
Flora, IL
Jennifer Venable (CFO)

**Cancer Centers of
Southwest Oklahoma**
Lawton, OK
Lane Hooten (COO)

**Central Oklahoma Family
Medical Center**
Konawa, OK
Nikole Taylor (DOP)

Coal County
Coalgate, OK
Trent Bourland (CEO)

340B Matters

**Comanche County
Memorial Hospital**
Lawton, OK
Brent Smith (CEO)

Gibson Area Hospital
Gibson, IL
Matthew Ertel (CFO)

**Harrisburg Medical
Center, Inc.**
Harrisburg, Illinois
J. Cody Sandusky, PharmD
(DOP)

Cordell Memorial Hospital
Cordell, Oklahoma
Bridget Cosby (CEO)

Hamilton General Hospital
Hamilton, TX
Eddie Read (CFO)

**Hayward Area Memorial
Hospital and Water's Edge**
Hayward, WI
Kent Dumonseau (CPA, CHFP)

Crawford Memorial Hospital
Robinson, IL
Stephen Blake Potts (DOP)

**Hamilton Memorial Hospital
District**
McLeansboro, IL
Victoria Woodrow (MBA,
CEO)

Henry County Medical Center
Paris, TN
Paula Bell (DOP)

Dimmit Regional Hospital
Carrizo Springs, TX
John Graves (CEO)

Hammond Henry Hospital
Geneseo, IL
Laura Domino (VP Patient Care
Physician Services)

Hopedale Medical Complex
Hopedale, IL
Emily Whitson (COO)

Ferrell Hospital
Eldorado, IL
Dallas Basinger (DOP)

**Hardeman County Memorial
Hospital**
Quanah, TX
Dennis Thomas (CEO)

Horizon Health
Paris, IL
Tiffany Turner (VP of Nursing
Services/CNO)

Franklin Hospital District
Benton, IL
James M. Johnson (CEO)

**Hardin County General
Hospital Clinic**
Rosiclare, IL
Roby D. Williams (Hospital
Administrator)

Illini Community Hospital
Pittsfield, IL
Kathy Hull (CEO)

Frio Regional Hospital
Pearsall, TX
John Hughson (CEO)

Genesis Medical Center
Aledo, IL
Heidi Hess (CNO)

**Harper County Community
Hospital**
Buffalo, OK
Kevin O'Brien (CEO)

**Illinois Critical Access
Hospital Network**
Princeton, IL
Pat Schou (FACHE Executive
Director)

340B Matters

**Illinois Pharmacists
Association**

Springfield, Illinois
Garth Reynolds (Executive
Director)

Mason District Hospital
Havana, IL

Penny Roch (DOP)
Doug Kosier (CEO)

Pana Community Hospital
Pana, IL

Michelle Foreman (DOP)

**Jackson County Memorial
Hospital**

Altus, OK
Steve Hartgraves (CEO)

Massac Memorial Hospital

Metropolis, IL
Lauren Scott (PharmD)

Perry Memorial Hospital

Princeton, IL
Rena Mathesius (DOP)

**Jordan Valley Community
Center**

Springfield, MO
Cliff Conquest (Grants/Special
Projects)

Memorial Hospital

Carthage, IL
Brett Bollman (CEO)

**Pinckneyville Community
Hospital**

Pinckneyville, IL
Kara Jo Carson (CFO)

Kirby Medical Center

Monticello, IL
Kim Alvis (CFO)

**Memorial Medical
Center, Inc.**

Ashland, WI
Kent Dumonseau (CPA, CHFP)

Rochelle Community Hospital

Rochelle, IL
Crystal D. Carty (DOP)

Knox County Hospital District

Knox City, TX
Stephen A Kuehler (CEO)

Midwest Medical Center

Glena, IL
Josh Feldman

Rush Copley Medical Center

Aurora, IL
Peter Couri (DOP)

**Lawton Community
Health Center**

Lawton, OK
Sean McAvoy (Executive
Director)

Mitchell County Hospital

Colorado City, TX
Leslie Tomlin (RPh)

Salem Township Hospital

Salem, IL
Kendra Kae Taylor (CEO)

Marshall Browning Hospital

DuQuoin, IL
Tracy Schubert

Newman Memorial Hospital

Shattuck, OK
Joe Neely (COO)

**Sarah Bush Lincoln Fayette
County Hospital**

Vandalia, IL
Gregory Starnes (CEO)

340B Matters

Sarah D. Culbertson
Memorial Hospital
Rushville, IL
Sarah Brockhouse (DOP)

Sparta Community Hospital
Sparta, IL
Meredith Klausing (DOP)

**Texas Organization of Rural
& Community Hospitals
(TORCH)**
Round Rock, TX
John Henderson (CEO)

**Thomas H. Boyd Memorial
Hospital**
Carrollton, IL
Kate Garner (CFO)

Valleywise Health
Phoenix, AZ
Anna Sogard (Executive
Director of Pharmacy)

Wabash General Hospital
Mt. Carmel, IL
Steve McGill (CFO)

Washington County Hospital
Nashville, IL
Jennifer Venable (CFO)