Examining Hospital Price Transparency, Drug Profits, and the 340B Program

Webinar

October 6, 2021
Speakers and Agenda

Speakers:
- Ted Okon, MBA, Executive Director, Community Oncology Alliance
- Aaron (Ronny) Gal, Ph.D., Moto Bioadvisors
- Robert Baird, RN, MSA, National Cancer Treatment Alliance

Agenda:
I. Welcome and introductions
II. Brief background on the 340B program
III. Report findings: 340B hospital transparency, drug pricing, and profits report
IV. Implications for stakeholders
V. Solutions?
VI. Questions?
Background on the 340B Program

Ted Okon, MBA, Community Oncology Alliance
Background on the 340B Drug Pricing Program

• **340B is a CRITICAL safety net program, including for patients with cancer that are uninsured or underinsured**
• Problem is the program has expanded from a handful of safety net providers to a booming money-maker for hospitals
  – Discounted 340B drug purchases reached $38 billion in 2020, 27% higher than in 2019 *(Source: Drug Channels)*
  – WAC list price value of 340B drug purchases was $80.1 billion in 2020 *(Source: IQVIA)*
• Use of contract pharmacy accounted for 30% of 340B drug purchases in 2020 *(Source: Drug Channels)*
  – The PBMs are now big contract pharmacy providers
    ▪ They understand how to make money from drugs and the value of 340B in doing so
• 340B hospitals have been on a land-grab to acquire independent oncology practices and other specialties using expensive drugs that are very profitable to 340B hospitals
  – Problem with consolidation is patients and payers (employers, Medicare, etc.) have much higher costs in the hospital setting
Examining Hospital Price Transparency, Drug Profits, & the 340B Program

Aaron (Ronny) Gal, Moto Bioadvisors
Examining Hospital Price Transparency, Drug Profits, & the 340B Program

Moto Bioadvisors

Aaron (Ronny) Gal, Ph.D.
Just how profitable are drugs for 340B hospitals?

• The 340B Drug Pricing Program was created in 1992 “to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”.

• The eligibility criteria for qualifying 340B institutions has been expanded several times. The largest group of participating entities in the 340B program have become disproportionate share hospitals (DSH). They represent 40 percent of U.S. hospitals and the value of the drugs purchased under the program was estimated at ~$38B (close to 10% of US drugs)

• As the 340B grew, it faced increasing criticism that (among others) the profits generated by hospitals is too large and too unaccountable vs. the public benefit achieved.

• However, while we had good idea how much drugs cost 340B institutions, we did not know how much they charged for the same drugs, it is thus difficult to estimate the amount of profit achieved by the hospitals

Source: CMS, Bernstein analysis
We now have regulation that provides hospital (drug) price transparency

• As part of the Affordable Care Act (ACA), Congress enacted section 2718(e) of the Public Health Service Act, which requires hospitals to “make public… a list of the hospital’s standard charges for items and services provided by the hospital.”

• CMS revised its guidance in November 2019, requiring hospitals, among other items, that hospitals publish a “machine-readable” file containing prices for all “items and services” provided by the hospital to patients for which the hospital has established a standard charge.

• These published prices must include (i) the chargemaster price, (ii) price for cash paying customers, (iii) de-identified minimum and maximum negotiated prices and, critically, (iv) payer-specific negotiated charges, which is the rate that a hospital has negotiated with each third-party payer.

Source: CMS, Bernstein analysis
The availability of transparent hospital prices offers an opportunity to make the debate on 340B hospitals more informed

- While there is no requirement for 340B hospitals to pass along the discounts they obtain (they may use their obtained discounts to fund operations or programs that benefit the community), it is certainly logical for them to do so.

- At the very least, one would expect a reasonable markup that allows the hospital to retain some of the profits for other programs, but also serves the (presumably lower income) local community interest in
  1. Obtaining lower cost insurance, as rates are dependent on local medical expenses, including drugs;
  2. Paying less out-of-pocket (OOP);
  3. For those who need to pay cash, obtain their drugs at an affordable rate.

- But do they?
~123 hospitals have effective data we can use

EXHIBIT 1. Waterfall of 340B Hospital Compliance With Transparency Regulations

1,087 Total 340B Hospitals
890 with price transparency file
876 in readable formats
327 are compliant with 2021 regulation
233 include drug prices
123 include individual plan names
(Hospitals used for study)

Only 123 of the 1,087 acute care 340B hospitals reached the finish line publishing individual negotiated payer price data for drugs.

These 123 hospitals formed the basis of our analysis.

Source: Bernstein analysis; hospital data
Yielding a decent size sample of prices

Of 123 hospitals with individual payer data, how many reported at least 1 price for each drug

As should be expected more datapoints for commonly used drugs

Source: Bernstein analysis; hospital data

The median hospital has prices for 22 drugs, across 16 commercial plans; overall we have ~55K data points
Five suggestions to reform the hospital data

- **Central data location.** Rather than posting files only on their website, hospitals should also upload the file into a central repository created by CMS where it can be accessed (analogous to standard shared-drive website).

- **Data qualification process.** CMS reviews the data for compliance with the regulation. A file must be readable with a standard format and contain required minimal data (names of services, individual payers).

- **Only report negotiated price data.** Move the hospital data from a database ‘dump’ to a price database — no other data, such as amounts billed to the payer or price modifier, are to be included.

- **Deepen data standardization.** The clearest benefit here would be a requirement to report products/services with their HCPCS codes and HCPCS unit sizes. Product description should have a unique and single cell used per data attribute.

- **Require specific data schema.** The current regulation defines which information ought to be published but does not specify the X-Y organization, order of data presentation, headers, terminology, and naming convention. It makes it virtually impossible to aggregate the data from different hospitals and compare without material manual adjustments.

Source: Bernstein analysis; hospital data
Summary of observation

- There is a ~3.8x median 340B Hospital Markup vs. 340B Hospital Discounted Acquisition Cost
  - Vs. WAC, prices are typically at 2x-3x
  - Spreads are much higher for products where prices declined over-time vs. their WAC

- There is a 5x gap between hospitals average allowable charges

- There is a narrower but still very material 2x-3x spread in allowable charges within the same hospital for the same drug

- **Conclusion**: the exposure of prices revealed very high mark-up of drug prices by 340B hospitals. Further, there is no ‘fairness’ - hospitals charge what they can negotiate vs. other hospitals and from different payers within the same hospital
Median 340B Hospital Markup vs. 340B Hospital Discounted Acquisition Cost Using 34% as the average discount of 340B drugs vs. the ASP

Spreads are higher for products facing competition
How much do 340B hospitals mark up drugs vs. WAC?

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Ratio of average commercial price to WAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Octreotide</td>
<td>4.5x</td>
</tr>
<tr>
<td>Eloxatin</td>
<td>4.0x</td>
</tr>
<tr>
<td>Belaplatin</td>
<td>3.5x</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>3.0x</td>
</tr>
<tr>
<td>Faslodex</td>
<td>2.5x</td>
</tr>
<tr>
<td>Epogen (Q4081)</td>
<td>2.0x</td>
</tr>
<tr>
<td>Belrapzo</td>
<td>1.5x</td>
</tr>
<tr>
<td>Trazurea</td>
<td>1.0x</td>
</tr>
<tr>
<td>Inflectra</td>
<td>0.5x</td>
</tr>
<tr>
<td>Velcade</td>
<td>0.0x</td>
</tr>
<tr>
<td>Retacrit (Q5106)</td>
<td>4.5x</td>
</tr>
<tr>
<td>Eligard*</td>
<td>4.0x</td>
</tr>
<tr>
<td>Retacrit (Q5105)</td>
<td>3.5x</td>
</tr>
<tr>
<td>Renflexis</td>
<td>3.0x</td>
</tr>
<tr>
<td>Belrapzo</td>
<td>2.5x</td>
</tr>
<tr>
<td>Trazurea</td>
<td>2.0x</td>
</tr>
<tr>
<td>Inflectra</td>
<td>1.5x</td>
</tr>
<tr>
<td>Velcade</td>
<td>1.0x</td>
</tr>
<tr>
<td>Retacrit (Q5105)</td>
<td>0.5x</td>
</tr>
</tbody>
</table>

Note: The graph shows the ratio of average commercial price to WAC for various drugs, with Octreotide having the highest ratio at 4.5x and Velcade having the lowest at 0.0x.
The spread achieved by hospitals on commercial insurers is disturbingly high

EXHIBIT 5. Price Breakdown of Darzalex Markups and Profit Across Care Settings and Payers

- **Community Oncology Practice**
  - Purchased for: $116,876
  - Reimbursed for: $123,889
  - Gains from treating a single patient for a year: +$7,013

- **Medicare Patient**
  - Purchased for: $76,320
  - Reimbursed for: $90,579
  - Gains from treating a single patient for a year: +$14,259

- **340B Hospital**
  - Purchased for: $76,320
  - Priced to Insurer: $290,016
  - Gains from treating a single patient for a year: +$213,696
EXHIBIT 6. Median Drug Prices at Individual 340B Hospitals vs. Median Across All 340B Hospitals

Median drug prices were calculated for each 340B hospital and compared to the median price of the drug across all 340B hospitals. The exhibit shows the dispersion of median hospital prices, i.e., 2.9 percent of hospitals charged less than 25 percent of Neulasta media price across hospitals.

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>&lt;25%</th>
<th>25.49%</th>
<th>50.79%</th>
<th>80-125%</th>
<th>126-200%</th>
<th>201-400%</th>
<th>401%+</th>
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</thead>
<tbody>
<tr>
<td>Neulasta</td>
<td>2.9%</td>
<td>18.3%</td>
<td>19.2%</td>
<td>26.9%</td>
<td>26.0%</td>
<td>3.8%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Remicade</td>
<td>5.4%</td>
<td>15.1%</td>
<td>15.1%</td>
<td>23.7%</td>
<td>19.4%</td>
<td>8.6%</td>
<td>12.9%</td>
</tr>
<tr>
<td>Avastin</td>
<td>5.4%</td>
<td>6.5%</td>
<td>21.7%</td>
<td>27.2%</td>
<td>30.4%</td>
<td>7.6%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Velcade</td>
<td>1.1%</td>
<td>12.0%</td>
<td>23.9%</td>
<td>34.8%</td>
<td>21.7%</td>
<td>5.4%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Alimta</td>
<td>1.1%</td>
<td>2.2%</td>
<td>28.1%</td>
<td>38.2%</td>
<td>24.7%</td>
<td>4.5%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Opdivo</td>
<td>2.4%</td>
<td>3.7%</td>
<td>18.3%</td>
<td>43.9%</td>
<td>23.2%</td>
<td>8.5%</td>
<td>0.0%</td>
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<tr>
<td>Herceptin</td>
<td>2.5%</td>
<td>10.1%</td>
<td>25.3%</td>
<td>34.2%</td>
<td>10.1%</td>
<td>17.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Keytruda</td>
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<td>7.7%</td>
<td>26.9%</td>
<td>34.6%</td>
<td>21.8%</td>
<td>9.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Kyprolis</td>
<td>2.6%</td>
<td>15.4%</td>
<td>23.1%</td>
<td>28.2%</td>
<td>14.1%</td>
<td>15.4%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Faslodex*</td>
<td>2.6%</td>
<td>22.1%</td>
<td>11.7%</td>
<td>29.9%</td>
<td>16.9%</td>
<td>11.7%</td>
<td>5.2%</td>
</tr>
<tr>
<td>Eligard</td>
<td>2.6%</td>
<td>23.7%</td>
<td>18.4%</td>
<td>13.2%</td>
<td>7.9%</td>
<td>21.1%</td>
<td>13.2%</td>
</tr>
<tr>
<td>Kadcyla</td>
<td>1.3%</td>
<td>3.9%</td>
<td>22.4%</td>
<td>43.4%</td>
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<td>5.3%</td>
<td>2.6%</td>
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<tr>
<td>Bendeka</td>
<td>6.7%</td>
<td>8.0%</td>
<td>21.3%</td>
<td>29.3%</td>
<td>13.3%</td>
<td>18.7%</td>
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<tr>
<td>Injectafer</td>
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<td>19.4%</td>
<td>11.1%</td>
<td>25.0%</td>
<td>29.2%</td>
<td>6.9%</td>
<td>4.2%</td>
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<tr>
<td>Erbitux</td>
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<td>26.4%</td>
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<td>15.3%</td>
<td>9.7%</td>
<td>4.2%</td>
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<tr>
<td>Rinixan</td>
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<td>4.2%</td>
<td>21.1%</td>
<td>46.5%</td>
<td>9.9%</td>
<td>9.9%</td>
<td>4.2%</td>
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<tr>
<td>Prolia</td>
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<td>19.7%</td>
<td>33.8%</td>
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<td>5.6%</td>
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<tr>
<td>Sandostatin Lar Depot</td>
<td>4.2%</td>
<td>8.5%</td>
<td>32.4%</td>
<td>23.9%</td>
<td>19.7%</td>
<td>4.2%</td>
<td>7.0%</td>
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<tr>
<td>Abraxane</td>
<td>1.4%</td>
<td>2.9%</td>
<td>32.9%</td>
<td>32.9%</td>
<td>18.6%</td>
<td>10.0%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Aranesp</td>
<td>1.5%</td>
<td>20.6%</td>
<td>16.2%</td>
<td>22.1%</td>
<td>27.9%</td>
<td>5.9%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Inflectra</td>
<td>5.9%</td>
<td>13.2%</td>
<td>14.7%</td>
<td>26.5%</td>
<td>19.1%</td>
<td>5.9%</td>
<td>14.7%</td>
</tr>
<tr>
<td>Udenyca</td>
<td>1.5%</td>
<td>21.2%</td>
<td>13.6%</td>
<td>45.5%</td>
<td>9.1%</td>
<td>4.5%</td>
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<td>Zarxio</td>
<td>4.9%</td>
<td>16.4%</td>
<td>19.7%</td>
<td>19.7%</td>
<td>26.2%</td>
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<td>Adectris</td>
<td>3.3%</td>
<td>3.3%</td>
<td>26.7%</td>
<td>35.0%</td>
<td>26.7%</td>
<td>5.0%</td>
<td>0.0%</td>
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<tr>
<td>Darzalex</td>
<td>0.0%</td>
<td>8.8%</td>
<td>19.3%</td>
<td>35.1%</td>
<td>19.3%</td>
<td>15.8%</td>
<td>1.8%</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td>2.8%</td>
<td>11.5%</td>
<td>21.2%</td>
<td>31.5%</td>
<td>20.0%</td>
<td>9.1%</td>
<td>4.0%</td>
</tr>
</tbody>
</table>

There is a wide spread of prices across 340B hospitals
Price spreads for the same drug within hospitals: Keytruda

EXHIBIT 7. Distribution of Keytruda Prices Within Hospital

KT1 – Kentucky Hospital 1
FL1 – Florida Hospital 1
NJ1 – New Jersey Hospital 1
NC1 – North Carolina Hospital 1
IN1 – Indiana Hospital 1
OH1 – Ohio Hospital 1
IN2 – Indiana Hospital 2
MA1 – Massachusetts Hospital 1
MA2 – Massachusetts Hospital 2
NC2 – North Carolina Hospital 2
OH2 – Ohio Hospital 2
WV1 – West Virginia Hospital 2
WV2 – West Virginia Hospital 3
IN3 – Indiana Hospital 3
NC3 – North Carolina Hospital 3
NC4 – North Carolina Hospital 4
NC5 – North Carolina Hospital 5
MN1 – Minnesota Hospital 1
NM1 – New Mexico Hospital 1
NM2 – New Mexico Hospital 2
Biosimilars in 340B institutions

• Biosimilars are arguable a way to reduce costs of oncology therapy

• However, biosimilar WAC prices are low, making them, discounts being equal, less attractive for 340B hospitals

• 340B hospitals thus tend to carry biosimilars less often
Biosimilar WAC prices are low, making them, discounts being equal, less attractive for 340B hospitals

### EXHIBIT 8. WAC Prices of Innovator Versus Biosimilar Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Brand</th>
<th>biosimilar (first)</th>
<th>biosimilar (second)</th>
<th>biosimilar (third)</th>
<th>biosimilar (fourth)</th>
<th>biosimilar (fifth)</th>
<th>biosimilar (sixth)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AVASTIN</strong></td>
<td>199.24</td>
<td>169.35</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>153.35</td>
</tr>
<tr>
<td>(1 mL of 25mg/1mL)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HERCEPTIN</strong></td>
<td>1558.42</td>
<td>1320.45</td>
<td>1402.50</td>
<td>Ogivri (Viatris)</td>
<td>Ontrusant (Merck/Bioepis)</td>
<td>Trazimera (Pfizer)</td>
<td>1324.66</td>
</tr>
<tr>
<td>(150 mg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1211.10</td>
</tr>
<tr>
<td><strong>RITUXAN</strong></td>
<td>93.95</td>
<td>84.56</td>
<td>84.56</td>
<td>Ruxience (Pfizer)</td>
<td>Riabni (Amgen)</td>
<td></td>
<td>71.68</td>
</tr>
<tr>
<td>(1 mL of 10mg/1mL)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>71.68</td>
</tr>
<tr>
<td><strong>NEULASTA</strong></td>
<td>6231.06</td>
<td>4175.00</td>
<td>4175.00</td>
<td>Ziestinzo (Sandoz)</td>
<td>Nyvepria (Pfizer)</td>
<td></td>
<td>3925.00</td>
</tr>
<tr>
<td>(0.6 mL of 6mg/0.6mL)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>EPOGEN</strong></td>
<td>165.80</td>
<td>Retacrit (Pfizer)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1 mL of 10000u/1mL)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>REMICADE</strong></td>
<td>1167.82</td>
<td>946.28</td>
<td>Renflexis (Merck/Bioepis)</td>
<td>753.39</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(100 mg)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
340B hospitals thus tend to carry biosimilars less often
340B hospitals do not discount products for cash paying or uninsured patients

Cash price markup from median price
Observation (I)

- The ‘spread’ between the discounted 340B purchase price and the price charged to insurers or patients in 340B hospitals is 3.8 times the median.

- 340B hospitals are not reducing prices they charge insurers or patients when their acquisition prices decline, negating efforts to reduce prices at the manufacturer level.

- There is pricing inconsistency between hospitals with some pricing drugs 2.0 times more than the median (i.e., 7.6 times their acquisition price or more) and even within hospitals, charges usually vary dramatically.

- 340B hospitals are slow to adopt biosimilars.

- Most problematic, 340B hospitals charge cash-paying customers the same as the median price of insurers, i.e., 3.8 times their acquisition costs to patients paying cash. In short, to the extent 340B institutions fulfill their mission of providing lower cost care, we are not seeing it reflected in their drug prices.
Observation (II)

• **The high profits on commercial patients creates market distortion.** It is much more profitable for 340B hospitals to treat commercial patients. A misaligned focus

• **Why have insurers not acted to reduce drug prices?** Insurers are aware of the gap between the price they pay and what CMS pays. Four reasons:
  • The balance in the negotiating position is often not on the insurers’ side.
  • Insurers have largely not focused on drug costs, but this is shifting
  • Insurers strategy is to shift usage to non-hospital settings rather than negotiate prices with hospitals.
  • Insurers are intermediaries. As long as they do not pay more than their peers and costs rise at a moderate enough rate to not cause disruption of the system, the have less imperative to act.

• **Transparency is necessary beyond the insurance layer.** Making drug prices visible to a broader cohort of stakeholders — primarily employers, but also regulators and the public will create some pressure on hospitals to control their prices

• **Will transparency be enough?** We are uncertain. The health care system has proven resistant to change across multiple dimensions even at the face of public scrutiny. It usually requires legislative or regulatory changes modifying the ‘rules of the road’ to get a change to take place.
Robert Baird, RN, MSA, National Cancer Treatment Alliance

Implications for Stakeholders
Implications for Stakeholders

• Employers/Purchasers
  ▪ Excess spending redirecting resources from other priorities
    – Chemotherapy costs 100% higher in HOPD than community oncology setting*
  ▪ Transparency will help employers understand the true cost of services
    – Multiple Business Groups on Health have assisted employers in transparency and other initiatives for cost saving strategies

• Employees
  ▪ Increased out of pocket costs for copay/co-insurance and reduced wages
    – Oncology costs continue to rise leading to increased copays/coinsurance**
    – RAND Study showed Hospital mergers lead to a $521 increase in hospital prices, a $579 increase in hospital spending among the privately insured population and a $638 reduction in wages.

• Providers
  ▪ Increased pressures to sell to/be acquired by hospitals
    – Oncologists very profitable to 340B Hospitals ($3-5 million net revenue per year on average)

Solutions? What can be done?

Ted Okon, COA
How to Address the Hospital Drug Problem

- HHS needs to significantly increase the penalties for hospital non-reporting
  - And data reporting needs to be in a uniform format (see report recommendations)
- Hospitals should not get 340B discounts – they should go directly to patients in need (uninsured and underinsured)
  - Ironically, the same “subsidy” system now in place with 340B – gross drug overpayments subsidize non/underpaid programs – caused Congress to change Medicare reimbursement, with the unintended consequence of fueling 340B
- Employers need to understand how much more they are paying for drugs (and medical care) at 340B hospitals and direct employees to high quality, lower cost sites of care managed by independent physicians
  - Employers should create opportunities for direct contracting with providers outside of hospital setting
    - Eliminate the middlemen sucking profits out of the system, further driving up costs
- The federal government needs to stop hospital consolidation, as mergers are driving up costs of drugs and medical care for all
Questions & Discussion

Type your questions into the Zoom Q&A panel!
Thank You and Stay in Touch!

- Full report available for download at www.CommunityOncology.org

- Slides and a recording will be distributed by email to those that RSVPd later this week.

- Subscribe to the COA newsletter for updates and breaking news!

- Continue the conversation at the COA Payer Exchange Summit on Oncology Payment Reform
  - Virtual meeting October 25-26, 2021
  - Cancer stakeholders share their experiences in efforts to advance oncology payment reform, increase value, and improve the patient experience
  - Learn more at www.PayerExchangeSummit.org
340B Drug Pricing Program Educational Briefing

Monday, November 1
2 p.m. ET

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