Executive Summary

Study Background: The Affordable Care Act (ACA) established new requirements for 501(c)(3) hospitals pertaining to their charity care policies. Hospitals self-report data related to these requirements on Internal Revenue Service (IRS) Form 990, which is submitted on an annual basis. Researchers from the University of Michigan, Ann Arbor and the University of California, Berkeley, recently published a study on hospitals’ compliance with these requirements in the New England Journal of Medicine (the “NEJM Study”) based on their analysis of IRS Form 990 data from 2012. The NEJM Study authors concluded that compliance with these requirements is mixed. Specifically, they observed that “[o]nly 44% of hospitals regularly notified patients of their potential eligibility for charity care before initiating debt collection, and just 29% reported charging patients who were eligible for charity care the amounts generally billed to insured patients.”

Focus on 340B Hospitals: Given that most 340B hospitals qualify for the program in part based on the number of Medicaid and low-income Medicare patients they serve, there is a presumption that these hospitals also provide relatively high levels of charity care such as free or discounted care to low-income uninsured or under-insured patients. However, studies on the amount of charity care provided by 340B hospitals suggest that many of these hospitals are providing relatively low-levels of charity or uncompensated care, including recent analyses by Avalere Health and the Medicare Payment Advisory Commission (“MedPAC”). Avalere found that fewer than one-third of 340B hospitals provide charity care that exceeds the national average and MedPAC concluded that 40 percent of 340B hospitals provide less than the median level (3.6 percent) of uncompensated care. In a separate study, the Government Accountability Office (“GAO”) found that, on average, 340B DSH hospitals provide greater levels of charity care than non-340B DSH hospitals. However, that analysis also found that some 340B hospitals provide relatively low levels of charity care.

Study Objectives and Findings: This study expands on the NEJM Study and has a twofold objective: (1) to measure and compare 340B and non-340B hospitals along the same measures as reported in the NEJM Study; and (2) to assess whether hospitals improved compliance with these requirements between 2012 and 2013. Using the same methodology published in the NEJM Study, this study analyzed 2012 and 2013 IRS Form 990 data and concluded the following:

1. 340B hospitals do not materially differ from non-340B hospitals in their compliance with new charity care requirements established in the ACA.

2. Hospital compliance with the new ACA requirements improved from 2012 to 2013; however, non-compliance with several measures still approaches or exceeds 40 percent for both 340B and non-340B hospitals.

3. Only 37 percent of 340B hospitals limited their charges for patients who were eligible for charity care to amounts generally billed to insured patients.

4. Less than 62 percent of 340B hospitals regularly notified patients of their potential eligibility for charity care before initiating debt collection.

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2 Alliance for Integrity and Reform (AIR 340B), Unfulfilled Expectations: An analysis of charity care provided by 340B hospitals (Spring 2014). Avalere Health performed supporting research and data analysis and compiled findings.
3 MedPAC, Assessing payment adequacy and updating payments: hospital inpatient and outpatient services (January 2016)
4 GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 2015).
Although the ACA did not place additional charity care requirements on 340B hospitals compared to other non-profit hospitals, according to health policy expert Sara Rosenbaum, the requirements on all non-profit hospitals added in the ACA resulted from “a series of Congressional hearings conducted by Republican and Democratic Members of Congress alike focused on excessive charges, the absence of financial assistance, and the use of exceptionally harsh billing and collections practices; these practices included stationing debt collectors in emergency departments, withholding treatment from people with outstanding bills for prior care, and imposing wage garnishment and liens.”

340B hospitals receive additional financial benefit through access to discounted drugs through the 340B Program. Given average savings of 27 percent and total hospital 340B purchases of approximately $10.7 billion in 2015, the estimated benefit to 340B hospitals is almost $4 billion. These study results demonstrate that hospitals, including 340B hospitals, fail to meet certain requirements established in the ACA that were intended to justify the financial benefit of their tax-exempt status.

**Introduction**

The Affordable Care Act added section 501(r) to the Internal Revenue Code, which established four new requirements for 501(c)(3) hospitals:

1. Establish written financial assistance and emergency medical care policies.
2. Limit amounts charged for emergency or other medically necessary care to individuals eligible for assistance under the hospital’s financial assistance policy.
3. Make reasonable efforts to determine whether an individual is eligible for assistance under the hospital’s financial assistance policy before engaging in extraordinary collection actions against the individual.
4. Conduct a community health needs assessment (“CHNA”) and adopt an implementation strategy at least once every three years. (These CHNA requirements are effective for tax years beginning after March 23, 2012 whereas the other requirements are effective for tax years beginning after March 23, 2010.)

These requirements were established in response to concerns raised about the levels of charity care provided by non-profit hospitals as compared to the value of their non-profit status. While three of the four requirements took effect shortly after the ACA was signed into law, the final regulations implementing these requirements were not published until December 29, 2014. Preceding this final rule, the IRS solicited comments and issued proposed rules and sub-regulatory guidance. Beginning in 2012, the IRS required that IRS Form 990s include reporting on most aspects of Section 501(r) requirements. The NEJM Study concluded that many hospitals failed to comply with several of these new requirements in 2012. In light of the additional financial benefits realized by hospitals participating in the 340B program, this study seeks to understand whether 340B hospitals differ from non-340B hospitals in complying with the new ACA requirements. Also, this study used the most recent data available

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7 Based on BRG analysis of total 340B drug purchases reported by the 340B Prime Vendor, Apexus.


from the IRS to assess whether hospital compliance with the ACA requirements improved between 2012 and 2013.

The final regulations implementing the new charity care requirements for 501(c)(3) hospitals also created enforcement measures to ensure hospitals have practices and procedures in place to facilitate overall compliance with the requirements. If a hospital organization fails to meet one or more of the new requirements with respect to one or more of its facilities, the hospital organization may have its 501(c)(3) status revoked unless it qualifies for an exemption. The ACA also created an additional penalty specifically for violation of the CHNA requirements under section 501(r)(3). A hospital that fails to meet the CHNA requirements will be subject to an excise tax equal to $50,000 unless it qualifies for an exemption. A hospital may be exempted from these enforcement actions under certain conditions, such as for minor omissions that are corrected promptly and unintentional failures.

Similar to the methodology described in the NEJM Study, this analysis focused on non-governmental, non-profit, short-term, acute care hospitals and excluded children’s and critical access hospitals. Using the IRS Form 990 data and the Medicare hospital cost report data in 2012, 1,723 hospitals were identified and matched. This is comparable to the 1,821 hospitals identified in the NEJM Study. Using the Health Resources and Services Administration’s Office of Pharmacy Affairs (“OPA”) 340B covered entity database, this study categorized the identified hospitals as 340B enrolled hospitals if they were enrolled in the 340B program for the entire duration of the calendar year. Hospitals that were enrolled only for a partial year were excluded from our analysis (64 in 2012 and 19 in 2013). Based on the hospitals’ self-reported IRS Form 990 data, this study developed similar metrics to those reported in the NEJM Study and compared results across years 2012 and 2013, as well as between 340B and non-340B enrolled hospitals. A more detailed description of the data relied upon and study methodology is presented in Appendices A and B.

**Results**

The study results are presented in two categories: comparison of 340B and non-340B hospitals and trends from 2012 to 2013. Similar to the NEJM Study, this study analyzed compliance with five categories of charity-care and debt-collection requirements on which hospitals self-report in IRS Form 990:

- Having written charity care and emergency medical care policies ("Written Charity and Emergency Care Policies")
- Basing maximum amounts that can be charged for individuals that qualify for financial assistance on commercial or Medicare rates ("Charges at Commercial/Medicare Rates")
- Not using extraordinary collection actions against patients before determining if they are eligible for financial assistance ("No Extraordinary Collection Action")
- Notifying patients of its financial assistance policy before initiating extraordinary collection actions ("Notification of Financial Assistance Policy")
- Conducting a Community Health Needs Assessment in the last three years ("Community Health Needs Assessment in Past 3 Years")

11 26 C.F.R. § 1.501(r)-2(a); see also 79 Fed. Reg. 79000 (Dec. 31, 2014)
12 Noncompliant hospital organizations that are trusts may be subject to an additional tax on the income, see 26 C.F.R. § 1.501(r)-2(d)
14 26 C.F.R. § 1.501(r)-2(b), (c).
15 See Appendix B for additional detail on the study methodology and comparisons of results of this study with the results published in the NEJM Study.
16 The four new hospital requirements established in section 501(r) to the Internal Revenue Code are self-reported across five distinct questions on Form 990 in IRS Form 990.
Comparison of 340B and Non-340B Hospitals

Figure 1 illustrates the results for the five charity-care and debt-collection requirements in 2012 and 2013, broken out by 340B versus non-340B status.

There is no meaningful difference in compliance with the new ACA requirements between 340B and non-340B hospitals. This is true for compliance with programmatic requirements (e.g., CHNA studies and written charity care policies) and requirements that have a direct financial impact on patients (e.g., Charges at Commercial/Medicare Rates, No Extraordinary Collection Action, and Notification of Financial Assistance Policy). For example, in 2013, 37.1 percent of 340B hospitals reported that they complied with the requirement to limit charges for those who qualify for financial assistance to no more than the Commercial or Medicare rates. In 2013, that percentage for non-340B non-profit hospitals was 36.6 percent.

Compliance Trends from 2012 to 2013

The first year in which hospitals were required to self-report compliance with the new requirements in the ACA was 2012, and the IRS has now made available data for both 2012 and 2013. Figure 2 illustrates the change in the percentage of all hospitals (340B and non-340B) self-reporting compliance with the new ACA requirements from 2012 to 2013.
Hospitals’ compliance with the new ACA requirements improved across all five categories evaluated as part of this study between 2012 and 2013. The largest increase (85 percentage points) was in the “Community Health Needs Assessment in Past 3 years” category, likely because this reporting requirement was phased in during 2012 (whereas other reporting requirements had gone into effect in earlier years). There was also a substantial increase (17 percentage points) in the percentage of hospitals notifying patients of charity care policies. However, the other two requirements with direct financial implications for indigent patients (Charges at Commercial/Medicare Rates and No Extraordinary Collection Action) only experienced modest increases of 5 to 6 percentage points. These results were consistent for both 340B and non-340B hospitals.

Conclusion

Similar to the NEJM Study results, this study found that hospitals’ compliance with the new ACA requirements for 501(c)(3) hospitals remains mixed. The vast majority of hospitals established written charity care policies (97 percent) and conducted a CHNA (98 percent) by 2013. However, only 37 percent of hospitals charged patients who were eligible for charity care amounts generally billed to insured patients, and only 60 percent of hospitals regularly notified patients of their potential eligibility for charity care before initiating debt collection. Compliance rates have improved between 2012 and 2013 across all categories; not surprisingly, the largest improvement was for completion of a CHNA for which there was an established financial penalty. However, overall, non-compliance with several measures still approaches or exceeds 40 percent for both 340B and non-340B hospitals. These findings were consistent across both 340B and non-340B hospitals despite the additional financial benefit 340B hospitals receive through access to highly discounted drugs.

Appendix A

The following datasets were incorporated into the analysis in this report:

**Schedule H Form 990 for tax years 2012 and 2013:** These datasets contain information reported by hospitals on their tax returns. The data are digitized and compiled by Guidestar (www.Guidestar.org). The data are used to determine if a hospital has established certain charity care– or debt collection–related policies as required by the ACA and reported to the IRS.

**Center for Medicare and Medicaid Services (“CMS”) Hospital Cost Reports for fiscal years 2012 and 2013:** These reports provide detailed financial information on all acute care hospitals that receive reimbursement from CMS for healthcare services provided to Medicare fee-for-service beneficiaries. The data are used to identify non-governmental, non-profit, short-term, acute care hospitals and to determine if the facility information found in the Schedule H Form 990 data is for a hospital or for another healthcare provider related entity that is not a hospital (e.g., a clinic).

**OPA 340B Covered Entity Database:** This database includes registration information for 340B covered entities and the timing of the registration. The data are used to determine if and when a hospital participates in the 340B program.
Appendix B

This appendix describes the methodology used to execute the analysis in this report and covers the following areas:

- Sample selection
- Policy category mapping
- Comparison to NEJM Study results
- 340B categorization

Sample Selection

To identify the sample of hospitals for analysis, this study adopted a methodology similar to the methodology described in the NEJM Study. The methodology involves aligning CMS cost report data to Schedule H Form 990 data to identify non-governmental, non-profit, short-term, acute care hospitals and excluding children’s and critical access hospitals. The sample selection process included the following steps:

- Use the CMS certification number to limit the sample of hospitals to those classified as short-term, acute-care hospitals.
- Use the provider control type value in the CMS hospital cost report data to limit the sample of hospitals to “Voluntary Nonprofit, Church” or “Voluntary Nonprofit, Other.”
- Extract hospital name and address information from the S-2 worksheet and exclude hospitals that are not located in one of the fifty states or in the District of Columbia.

The results of the matching process identified 1,723 facilities in 2012 and 1,422 hospitals in 2013. The smaller hospital sample in 2013 is attributable to data deficiencies in the 2013 IRS Form 990 data collected by Guidestar.

Policy Category Mapping

The study analysis required mapping values found in the Schedule H Form 990 data to five policy categories. Below are the details of the mapping process, using the 2012 Schedule H Form 990 as a reference:

- **Written Charity and Emergency Care Policies**
  - For hospitals with facility-level data, code the hospital as having the policy if Part V B, question 9 was answered “Yes” and Part V B, question 19 was answered “Yes.”
  - For hospitals without facility-level data, code the hospital as having the policy if Part I, question 1b was answered “Yes.”
  - Code all other hospitals as not having the policy.

- **Charges at Commercial/Medicare Rates**
  - Code the hospital as having the policy if Part V B, question 20, box a, b, or c was answered “Yes.”
  - Code all other hospitals as not having the policy.
• No Extraordinary Collection Action
  - Code the hospital as not having the policy if Part V B, question 16, box a, b, or c, or Part V B, question 17, box a, b, or c, was answered “Yes.”
  - Code all other hospitals as having the policy.
• Notification of Financial Assistance Policy
  - Code the hospital as not having the policy if Part V B, question 18, box a, b, or c was answered “Yes.”
  - Code all other hospitals as having the policy.
• Community Health Needs Assessment in Past 3 Years
  - Code the hospital as having the policy if Part V B, question 1 was answered “Yes.”
  - Code all other hospitals as not having the policy.

This process is similar to the methodology used by the NEJM Study, with one key difference: for the “Written Charity and Emergency Care Policies” category, if the hospital did not have facility-level information, this study used the information found on Part I of the Schedule H 990 data that reports at the organization level to assess if the hospital had a written financial assistance policy (similar to the NEJM Study). However, this study did not require the question regarding the policy applying uniformly to all hospital facilities (Part I, question 2) be answered “Yes.”

**Comparison to NEJM Study Results**

The results of this analysis for the 2012 tax year are very similar to NEJM study results. The table below compares the two sets of results:

<table>
<thead>
<tr>
<th>Policy Category</th>
<th>NEJM Results</th>
<th>BRG Results</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written Charity and Emergency Care Policies</td>
<td>94.1%</td>
<td>95.6%</td>
<td>-1.5%</td>
</tr>
<tr>
<td>Charges at Commercial/Medicare Rates</td>
<td>29.4%</td>
<td>30.4%</td>
<td>-1.0%</td>
</tr>
<tr>
<td>No Extraordinary Collection Action</td>
<td>80.0%</td>
<td>79.9%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Notification of Financial Assistance Policy</td>
<td>44.0%</td>
<td>44.1%</td>
<td>-0.1%</td>
</tr>
<tr>
<td>Community Health Needs Assessment in Past 3 Years</td>
<td>10.6%</td>
<td>12.5%</td>
<td>-1.9%</td>
</tr>
</tbody>
</table>

The differences range from −1.9 percent to 0.1 percent and could potentially be explained by the different underlying hospitals in the respective samples. The NEJM Study reported a sample of 1,821 hospitals, while this study was based on a sample of 1,723 hospitals.

**340B Categorization**

To classify hospitals by 340B status, this study relied on information found in the OPA 340B covered entity database. The following steps determined 340B status:
• Limit the OPA database to the main or parent facilities actively enrolled in the 340B program for the entirety of calendar year 2012 or calendar year 2013.

• Use the CMS certification number from the CMS cost report data to link to the Medicare Provider Number field in the OPA database.

• For each sample (2012 and 2013), categorize hospitals as 340B if the hospital was enrolled during the entire calendar year and as non-340B if the hospital did not participate in the 340B program for all or part of the calendar year.

  – Due to partial year participation in the 340B program, 64 hospitals in 2012 and 19 hospitals in 2013 were excluded entirely from this analysis.

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