Key Issue Papers

These papers provide an overview of the current federal priorities for California hospitals and illustrate our hospitals' and health systems' commitment to providing high-quality, efficient and affordable health care to all Californians, and outline what hospitals need to meet that commitment.

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2018 Priority Messages for Congress from California’s Hospitals

Medicare DSH and Worksheet S-10

340B Drug Pricing Program is Essential to Helping Safety-Net Providers Serve Patients and Communities

Intravenous Opioid Shortage
Priority Messages for Congress from California’s Hospitals

**340B Drug Discount Program**
- 175 safety-net hospitals rely on savings from the 340B program to extend critical services to their communities.
- The 340B program does not impact the federal budget or use taxpayer dollars.
- California hospitals have been exemplary stewards of the program and support efforts to ensure program integrity.

**Intravenous Opioid Shortage**
- California hospitals support efforts to address the opioid epidemic and partner with community resources to provide care to those with addiction challenges.
- Selective injectable intravenous (IV) opioid use in hospitals is a critical component of quality care and pain management.
- The shortage of injectable IV opioids impacts patient safety and patient care.
- The Drug Enforcement Agency has limited the release of these critical resources and should allow an increase in quotas for manufacturers to meet the needs of health care providers caring for patients.

**Medicare Disproportionate Share and Worksheet S-10**
- Worksheet S-10 has become the nationwide source for hospital uncompensated care data. Therefore, it is imperative that CMS ensure its accuracy.
- Recent analysis of the current Worksheet S-10 data demonstrates that it remains neither reliable nor valid for use in redistribution of Medicare disproportionate share hospital (DSH) uncompensated care dollars.
- Significant unexplainable anomalies and distortions remain in the data.
- Data reliability and validity should be CMS’ highest priority when making critical decisions about redistributing scarce resources to safety-net providers.
- Worksheet S-10 data must be audited to ensure reliability and validity prior to its continued use for Medicare DSH calculations.
- Additional time is needed for hospitals to comply with new cost reporting instructions prior to data being used for payment purposes.

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Medicare DSH and Worksheet S-10

Issue

The Centers for Medicare & Medicaid Services’ (CMS) federal fiscal year (FFY) 2018 inpatient prospective payment system final rule included policies for implementing Medicare disproportionate share hospital (DSH) payment cuts, as required by the Affordable Care Act (ACA). These cuts have been devastating for many hospitals and health systems across California. Despite overwhelming concern expressed by hospitals across the country, including analysis of the devastating cuts that would result, CMS finalized its proposal to use the Medicare cost report’s Worksheet S-10 and its reporting of hospital uncompensated care as the basis for calculating and redistributing the Medicare DSH uncompensated care payments. In response to comments, CMS revised the instructions on September 29, 2017, and gave hospitals a very short period to amend their 2014 and 2015 cost reports.

Recent analysis of the current Worksheet S-10 demonstrates the data remains neither reliable nor valid for use in redistribution of Medicare DSH uncompensated care dollars. Significant unexplainable anomalies and distortions in the data remain. Data reliability and validity should be CMS’ highest priority when making such critical decisions about scare resources. Because there is not a process to review or appeal reallocation of DSH funds, data reliability and validity should be the agency’s highest priority when making such critical decisions about scarce resources.

Position

Due to the volatility of the data reported on Worksheet S-10, we do not support its continued use at this time. Rather, CMS should reconsider its proposed policies, take time to promote shared understanding for reporting and further educate providers on these revisions. Most importantly, CMS must engage its contractors in a hospital-specific audit to ensure reliability and validity before the data is more widely used in calculating Medicare DSH uncompensated care payments. While a step in the right direction, CMS’ stated intention to begin desk audits of Worksheet S-10 for FFY 2017 cost reports will not happen soon enough. By default, Worksheet S-10 has become the nationwide source for hospital uncompensated care data — and therefore it is imperative that CMS ensure its accuracy.

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Medicare DSH and Worksheet S-10 Reduction (cont.)

- **Worksheet S-10 has become the nationwide source for hospital uncompensated care data — it is imperative that CMS ensure its accuracy.**
- **Analysis of the current Worksheet S-10 demonstrates the data remains neither reliable nor valid for use in redistribution of Medicare DSH uncompensated care dollars.**
- **Significant unexplainable anomalies and distortions in the data remain.**
- **Data reliability and validity should be CMS’ highest priority when making such critical decisions about redistributing scarce resources to safety-net providers.**
- **Worksheet S-10 data must be audited to ensure reliability and validity prior to its continued use for Medicare DSH calculations.**
- **Additional time is needed for hospitals to comply with new cost reporting instructions, prior to data being used for payment purposes**

**Analysis**

Due to concerns over data variability and lack of reporting experience with Worksheet S-10, which details hospital uncompensated care, CMS has used Medicaid and Medicare SSI days as a proxy for uncompensated care in Factor 3 since FFY 2014. However, in the FFY 2018 IPPS proposed rule, CMS stated that it found an improving correlation between Factor 3 values calculated using Worksheet S-10 data and the Schedule 990 and those calculated using proxy data. Thus, CMS finalized its proposal to phase in the use of Worksheet S-10 data over three years, starting with FFY 2014 cost reports for DSH payments in FFY 2018. In the FFY 2019 inpatient prospective payment system proposed rule released on April 24, CMS continues its proposed three-year transition to the use of Worksheet S-10 and proposes to utilize the FFY 2014 and 2015 cost reports along with one year of proxy data. CMS does note it is considering using only one year of data going forward. Importantly, CMS and its Medicare administrative contractors continue to work with hospitals to address aberrant data. CMS traditionally uses the March release of the cost report data for the inpatient prospective payment system final rule; however, the agency notes it is considering using data available in May to calculate the final uncompensated care adjustment factors.
340B Drug Pricing Program is Essential to Helping Safety-Net Providers Serve Patients and Communities

- **Issue**

  More than 25 years ago, Congress established the 340B Drug Pricing Program to provide safety-net hospitals with financial relief from high prescription drug costs. No state or federal dollars are spent on the program and there is no cost to taxpayers. Under the 340B program, pharmaceutical manufacturers participating in Medicaid sell outpatient drugs at discounted prices to health care organizations that care for significant numbers of uninsured and low-income patients. In California, 175 hospitals rely on 340B savings to maintain access to critical health services in their communities. Qualifying 340B entities include community health centers, children’s hospitals, hemophilia treatment centers, critical access hospitals, sole community hospitals, rural referral centers and public and nonprofit disproportionate share hospitals that serve low-income and indigent populations.

- **Position**

  The 340B Drug Pricing Program is essential to helping safety-net providers stretch limited federal resources to better serve their patients and communities. CHA is strongly opposed to any efforts to scale back or reduce the program’s benefits. California hospitals have been exemplary stewards of the 340B program for decades and support program integrity efforts to ensure this vital program remains available to safety-net providers.

- **Analysis**

  Many 340B hospitals are the health care safety net for their communities. The program generates valuable savings for eligible hospitals to reinvest in programs that enhance patient services and access to care. While many hospitals use 340B savings to provide free or reduced-price prescription drugs to vulnerable patient populations, the savings also allow hospitals to continue providing a wide array of patient services and programs. For example, hospitals use 340B savings to provide free care for uninsured patients, free vaccinations, services in mental health clinics, medication management programs and community health programs.

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**Issue**

Hospitals and health systems are facing a critical shortage of injectable intravenous (IV) opioid medications — including morphine, hydromorphone and fentanyl — that are used in a variety of practice settings to treat acute or chronic pain. Injectable IV opioids are critical to treating pain needs of patients undergoing interventional procedures, pre- and post-operative procedures, intensive critical wound treatment, surgeries and procedures that would otherwise require general anesthesia. Often, hospitals rely on these drugs to treat patients who cannot take oral opioid medications. These medications are also frequently used in intensive care units for surgical, trauma, burn or oncology patients when it is not clinically appropriate to use oral opioids. A diminished supply of these critical drugs — or no supply at all — prevents patients from getting the care they need.

The shortage of these medications is largely attributable to manufacturing delays and the Drug Enforcement Administration’s (DEA) decision to reduce quotas for opioid manufacturers. The quota reduction — 25 percent in 2017 and 20 percent in 2018 — is intended to respond to recent opioid crises by balancing the production of products needed for legitimate use against the production of an excessive amount of potentially harmful substances. Pfizer, which manufactures over 60 percent of injectable IV opioids, recently stopped production due to manufacturing issues and voluntarily surrendered a portion of its quota allotment. The DEA reallocated this allotment to three DEA-registered manufacturers, but — because they do not primarily produce injectable IV opioids — there is no guarantee that their production will happen quickly enough to make up for massive backorders before Pfizer’s projected reopening in 2019.

**Position**

The severe shortage of injectable IV opioids threatens patient care in hospitals and surgical centers. CHA shares the DEA’s concern that these medications are well managed, particularly in light of the national opioid epidemic. We fully support efforts to stem the opioid epidemic and advocate use of alternate and advanced pain management techniques, as well as safe and judicious opioid use. However, selective administration of injectable IV opioids remains an essential component of patient pain management.

Hospital and health system access to these drugs in a timely manner is critical to safe, efficient patient care. We urge the DEA to continue to use its discretionary authority to review production quotas and to implement any other procedures necessary until the shortage resolves.

**Analysis**

When faced with the dilemma of medication shortages such as this, hospitals work long hours to find alternatives. When unable to use the injectable IV opioid of choice, prescribers are forced to order whichever injectable IV opioid is available. However, because dosing equivalency between the injectable IV opioids differs significantly, the risk of medication errors increases. Moreover, using a more potent opioid based on lack of supply alone defeats national efforts to use these drugs only when absolutely necessary.