

# Mergers threaten health care delivery

By David Balto

As consumers suffer from escalating premiums and reduced services from their health insurers, they face a simple truth — a lack of health insurance competition threatens the delivery of health care. Health insurance competition in California is fragile at best. According to the California Health-Care Foundation, insurance markets are highly concentrated with three insurers controlling 83 percent of the small market and 75 percent of small/large group markets.

Unfortunately, this will get much worse unless California regulators act. Along with the recently approved merger of Blue Shield of California with Care1st Health Plan, there are three significant pending health insurance mergers: Anthem-Cigna, Aetna-Humana, and Centene-Health Net. Combining all three transactions, the mergers will harm over 7 million enrollees throughout California in a variety of insurance products including commercial, administrative-services only plans, Medicare Advantage, and Medicaid Managed Care.

Have no doubt, there will be a significant loss of competition from these consolidations. As Consumer Action informed the California Department of Managed Health Care, the Aetna-Humana transaction would reduce competition for Medicare Advantage plans in eight separate counties, including Los Angeles and San Diego. A recent report by Health Affairs found that the merger of Anthem-Cigna would not only diminish competition in certain commercial markets but would also substantially lessen competition for self-insured employers in the administrative-services only market. The



Protesters outside the offices of Blue Shield of California in El Segundo in 2014.

er physicians and other providers in underserved areas, longer wait times, assembly line medicine, and preventing providers from providing the full range of services consumers need and desire. The motivations of insurance companies are to provide as little service at the highest price to increase profits. As Judge Richard Posner once observed, an insurance company's "incentive is to keep you healthy if it can, but if you get very sick, and are unlikely to recover to a healthy state involving few medical expenses, to let you die as quickly and cheaply as possible."

Along with reducing services and driving providers out of the market, health insurers increasingly coerce consumers into narrow networks. According to the Leonard Davis Institute of Health Economics and the Robert Wood Johnson Foundation, 75 percent of all individual plans offered in California use a narrow network that only includes 25 percent or fewer of all area providers. These mergers would enable even less access by eliminating providers from a network or cutting off access to patients' preferred health care providers.

Lastly, these mergers can deteriorate health care innovation. The Patient Protection and Affordable Care Act was passed to not only to ensure an increase in consumer participation in health insurance markets, but also to drive providers and insurers to improve health care. However, by eliminating competition in insurance markets and driving down reimbursement below competitive levels, industry experts have noted that the mergers could very well undercut this much-needed innovation.

The parties also claim astronomical benefits from the mergers, but none of the previous mergers had

led to lower premiums. Cutting staffing, reducing services, and coercing consumers into more restricted networks is no plus for consumers.

California consumers need the strongest response. Fortunately, California Insurance Commissioner Dave Jones has raised concerns about the mergers and concentration within health insurance markets. Both the California Department of Managed Health Care and the California Department of Insurance has or will hold hearings on each of these three mergers. Most importantly, both departments are committed to a public, transparent process in which consumers can voice their concerns. And, California Attorney General Kamala Harris is actively involved in a multistate investigation.

All of the state regulators and enforcers need to take the strongest action to protect consumers. The future of competitive health insurance is at stake.

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## Transparency comes with costs under the Sunshine Act

By David Kirman  
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Did you know there is a publicly accessible website where you can see how much money pharmaceutical and medical device manufacturers pay your doctor and possibly even your hospital? There is. The Physician Payments Sunshine Act requires pharmaceutical and medical device manufacturers to report to the Centers for Medicare and Medicaid Services (CMS) most payments and transfers of value made to physicians and teaching hospitals. Congress passed the Sunshine Act to encourage financial transparency and to reveal relationships between the pharmaceutical industry and doctors. CMS has an official website for its reporting program called Open Payments, available at <https://www.cms.gov/openpayments/>.

Since this data was first published in 2014, CMS has documented almost \$10 billion paid by the pharmaceutical industry to physicians. This money was paid by 1,617 companies and to 683,000 physicians. While most of these transfers of value were for typical expenses, such as research, education and consulting, the data has nevertheless resulted in striking headlines such as "Latest Sunshine Bombshell: \$6.5B in doctor-and-hospital payments last year," "Is Your Doctor Taking Bribes from Drug Companies," and "Drug Company Enlists Doctors Under Scrutiny."

To be sure, the Sunshine Act has important business and legal ramifications, and there are several ways that consumers, the press, whis-

tleblowers and law enforcement are using — or not using — the data.

Under the Sunshine Act, "Applicable Manufacturers" must generally report all direct and indirect "value transfers" to "covered recipients." An applicable manufacturer is an entity operating in the United States that is: (i) engaged in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological or medical supply, or (ii) is under common ownership with an entity in paragraph (i) and provides assistance or support to such entity with respect to the covered product. A "covered recipient" includes U.S.-licensed physicians and teaching hospitals. Medical students, physicians assistants and nurses are not "covered recipients" for the purpose of the Sunshine Act. The act exempts certain value transfers from being reported, including certain educational materials, speaker fees for accredited continuing medical education programs, discounts, rebates and small payments of less than \$10 when a covered recipient received less than \$100 annually.

Both direct and indirect transfers of value must be reported. While direct payments to physicians and teaching hospitals are typically reportable, indirect payments frequently require closer examination. Indirect payments are any payment made to a third party where the payor directs the third party to provide the payment to a covered recipient. When an applicable manufacturer is unaware that a covered recipient will receive payment, the applicable manufacturer has no reporting duty, because it did not intend or expect that a covered recipient would re-

### The Facts About Open Payments Data



A screenshot of information provided on the Open Payments website.

ceive any portion of the payment. Whether an applicable manufacturer is "unaware," however, is sometimes difficult to determine and requires an analysis of the specific facts of the transfer of value. A manufacturer "knows" of the physician covered recipient who receives the indirect payment if it has actual knowledge of the identity of the recipient or acts in deliberate ignorance or reckless disregard of the recipient's identity. This "knowledge" standard does not create an indefinite obligation on manufacturers to ascertain whether any doctors or teaching hospitals received indirect payments; CMS created a clear cut-off date of six months into the next reporting year to put an end to the applicable manufacturer's duty to identify any potential covered recipients for an indirect payment.

While CMS's guidance is a helpful starting point as to when indirect payments must be reported, many questions remain. A general rule of thumb is that payments earmarked for use by physicians or teaching hospitals — covered recipients —

need to be reported, while unrestricted transfers of value do not. Thus, if any portion of the payment will be received by a covered recipient, it must be reported. Similarly, if an applicable manufacturer directs payments to a discrete set of covered recipients whose identities the manufacturer may not actually know but could easily ascertain, then the Sunshine Act does not allow the manufacturer to turn a blind eye. It requires these payments to be reported.

While the Sunshine Act has increased transparency, it also has business and legal ramifications. Compliance is a significant burden for manufacturers and businesses. The cost of collecting, maintaining and organizing data for Sunshine Act reporting purposes has made a noticeable dent in budgets — including legal and compliance budgets. And while the Open Payments website empowers consumers by permitting them to review what pharmaceutical and medical device manufacturers are paying their doc-

tors and teaching hospitals, this data is not easy to unpack. CMS requires manufacturers to classify the type of data being reported into various "nature of payment" categories, but it is difficult to understand the meaning behind the types of payments reported under some of these broad categories, such as "consulting fees" or "honoraria." And while it remains to be seen how useful the data will be to the typical consumer, it has resulted in striking articles and will provide additional data for law enforcement and whistleblowers to investigate kickbacks and bribes.

Moreover, the public's perception of the data could have a chilling effect on beneficial transactions, such as research payments, education and charitable contributions. Reporting requirements for these types of payments have made doctors and hospitals hesitant to accept some transfers of value from manufacturers, because they fear the potential appearance of impropriety that may be associated with accepting such payments. Such hesitancy could

stifle many productive and useful transfers of value which are made to covered recipients for scientific advancement, medical research, and education.

Regardless of the implications, the Sunshine Act or some future version of the law appears to be here to stay, and its resulting data will remain subject to scrutiny. An individual at every applicable manufacturer is required to attest to the validity of their data. Failure to report could result in civil penalties and known falsification of data could implicate a number of criminal laws. As such, applicable manufacturers should take reporting seriously and invest the necessary resources to comply with the Sunshine Act, including appropriate legal and factual analysis of areas where reporting obligations are ambiguous. Applicable manufacturers should also proactively analyze their data through the lens of a whistleblower or law enforcement investigator to reveal any spending that could be perceived — rightly or wrongly — as a violation of the federal Anti-Kickback Statute or Foreign Corrupt Practices Act. While the analysis will vary, it could include benchmarking against competitors, analyzing outliers, monitoring significant changes in spending, looking for unexplained trends or anomalies in spending, and evaluating the license and practice areas of doctors receiving payments to determine their appropriateness to receive money or benefits. Applicable manufacturers may also look at other applicable manufacturers' data for competitive purposes and assess whether their competitors' spending appears appropriate.

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