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IDSA
Infectious Diseases Society of America

February 6, 2009

BY ELECTRONIC SUBMISSION

Ms. Charlene Frizzera, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: File Code CMS-1403-FC; CMS-1270-F2
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on the Physician Self-Referral Exception for Incentive Payment and Shared Savings Programs [File Code: CMS–1403–FC; CMS–1270–F2]

Dear Acting Administrator Frizzera:

The Infectious Diseases Society of America ("IDSA") appreciates this opportunity to comment on the Center for Medicare and Medicaid Services' ("CMS") "Exception for Incentive Payment and Shared Savings Programs" in the Calendar Year 2009 Physician Fee Schedule Final Rule with Comment Period.[1] IDSA believes that an exception to the physician self-referral ("Stark") law[2] for incentive payment and shared savings programs can, if drafted with sufficient flexibility, remove existing impediments to hospitals' ability to incentivize physicians to help implement and maintain infection control and prevention strategies and procedures.

IDSA represents over 8,000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases ("ID"). The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. ID physicians are involved in direct patient-care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, those with cancer or with transplants who have life-threatening infections caused by unusual microorganisms and new and emerging infections, such as severe acute respiratory syndrome ("SARS") and influenza. ID physicians also work regularly with hospitals to design, implement and oversee infection-control protocols as well as antimicrobial-management programs, which are concerned with limiting adverse drug reactions and stemming the emergence of multidrug-resistant organisms.

[1] 73 Fed. Reg. 69726 (Nov. 19, 2008).
[2] 42 U.S.C. § 1395nn; 42 C.F.R. § 411 Subpart J.

Infection control and prevention is a key part of any hospital's effort to improve patient-care as well as reduce costs. A robust and effective infection control and prevention program not only may prevent patient morbidity and mortality from infectious complications, but also can save an institution and the overall healthcare system significant resources. In fact, the Centers for Disease Control and Prevention ("CDC") estimates hospital-acquired infections add nearly $5 billion to U.S. health care costs every year.[3] In addition, a 2007 study found that, in 2002, 1.7 million hospital-acquired infections were associated with 99,000 deaths.[4] CMS' recently finalized payment policy for hospital-acquired conditions ("HACs"), including several infections, no longer pays additional costs of hospitalization associated with selected conditions that were not present on admission.[5] This payment policy implicitly recognizes how critical it is for hospitals to adopt infection control and prevention procedures. As CMS has noted, "Research has . . . shown that hospitals are not following recommended guidelines to avoid preventable hospital-acquired infections," as evidenced by, among other things, a 2007 survey that found that 87 percent of hospitals surveyed do not follow recommendations to prevent many of the most common hospital-acquired infections.[6]

To be successful, an infection control and prevention program requires all hospital personnel to follow the recommended clinical practice protocols. Accordingly, IDSA recommends that CMS adopt a specific exception for "incentive payment" and "shared savings" programs to allow hospitals to collaborate with and pay ID and other physicians (as an incentive for meeting recognized quality benchmarks that demonstrate success in the infection control and prevention arena. In doing so, IDSA respectfully requests that CMS consider the following comments.

I. Hospitals should be permitted to share cost savings derived from quality-enhancing as well straight cost-reducing programs.[7]

In its preamble discussion, CMS suggests that different, if not more rigorous, conditions to prevent risk of program or patient abuse may need to be included in an exception for programs, such as traditional gainsharing, where payments to a physician are made for reducing or limiting items or services furnished to Medicare or Medicaid beneficiaries under a physician's

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[3] Medicare Hospital Inpatient Prospective Payment System Final Rule for FY 2009, 73 Fed. Reg. 48434, 48471 n.3 (Aug. 19, 2008) (citing CDC: Press Release, March 2000. Available at: http://www.cdc.gov/od/oc/media/pressrel/r2k0306b.htm).

[4] 73 Fed. Reg. at 48471 n.4 (citing Klevens et al., Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. Public Health Reports. March–April 2007. Volume 122).

[5] See 73 Fed. Reg. at 48471-91.

[6] 73 Fed. Reg. at 48471 (citing 2007 Leapfrog Group Hospital Survey, The Leapfrog Group 2007. Available at: http://www.leapfroggroup.org/media/file/Leapfrog_hospital_acquired_infections_release.pdf).

[7] This section generally addresses CMS' solicitation of **Comments #1** and **#2** (regarding the terminology "incentive payment" and "shared savings"), **Comment #6** (regarding whether a program involving cost savings measures that also improve quality should be treated as an incentive payment or shared savings program), **Comments #7 and #8** (regarding "incentive payment programs" that would not involve payments to reduce or limit services) and **Comment #9** (regarding the utility of an exception that incorporates conditions that have appeared in favorable Office of Inspector General ("OIG") gainsharing advisory opinions). This section also generally addresses **Comment #34** (regarding the calculation of the amount of total cost savings available for distribution under a shared savings program).

direct care.[8] CMS attempts to capture these traditional gainsharing arrangements under a broad definition of "shared savings," defined by the agency as including any program that offers "physicians a share of the hospitals' variable cost savings attributable to the physicians' efforts in controlling the costs of patient care by eliminating or reducing unnecessary services or procedures."[9] Unfortunately, infection control and prevention procedures do not fit neatly into this traditional definition of gainsharing.

IDSA requests that CMS expand its gainsharing definition to recognize a wider variety of quality enhancing and cost-saving programs, including those that are focused on reducing or preventing avoidable hospital complications. By their design, infection control and prevention programs are not focused on reducing items or services at the patient level but rather are focused on improving systems of care at the institution level.

A. CMS definitions.

CMS has attempted to group the various types of programs that use economic incentives to foster high quality and cost-effective care into two types — "incentive payment" and "shared savings" programs. As described by CMS, incentive payment programs include: "pay for performance," "quality-based purchasing," and "quality improvement and reimbursement methodolog[ies] aimed at moving towards payments that create strong financial support for patient focused, high value care."[10] Shared savings programs include: "'gainsharing' and other cost savings and waste reduction programs [that] seek to align physicians' economic incentives with those of hospitals . . . ."[11] These traditional gainsharing programs often involve hospitals sharing a percentage of savings realized when physicians adopt hospital-prescribed protocols that require them to standardize their use of certain products or their approach to treating certain conditions in ways that are intended to reduce the hospitals' costs. CMS also defines shared savings programs to include "hybrid programs that involve both the sharing of cost savings and payments for improvement or maintenance of patient care quality."[12] IDSA encourages CMS to include in its description of incentive payment programs those quality-focused programs that "involve the sharing of cost savings from the reduction of waste or changes in administrative or clinical practice at the system level that result in improved patient outcomes."[13]

Hospitals can improve quality and realize cost savings at the system level by following preestablished infection control and prevention procedures that are based on nationally recognized standards and designed to meet local infection reduction or prevention targets. The fact that payments for meeting these targets are based on the savings achieved, or costs avoided, by the hospital should not preclude their inclusion in shared savings and incentive payment programs.

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[8] See generally, 73 Fed. Reg. at 69795.
[9] 73 Fed. Reg. 38502, 38549 (July 7, 2008).
[10] Id.
[11] Id.
[12] 73 Fed. Reg. at 69794.
[13] 73 Fed. Reg. at 69794.

B. Calculating hospital cost savings.

This concept of hospital "savings" is very common in the infection control and prevention arena. Health economists are able to calculate the healthcare related cost-savings associated with decreases in the number of bloodstream infections in medical intensive care units when ID specialists direct and implement patient-care, antimicrobial-management, and infection-control programs. In a recent study, the excess direct hospital costs per each nosocomial infection were estimated at an average of $15,275, with collateral costs totaling an estimated $38,600.[14] ID physicians use the collection of baseline data to determine a starting point for measurement and use data collection throughout the course of the program, and at the endpoints, to assess whether quality benchmarks rates have been met. These same data that demonstrate that a program has led to improved patient outcomes in the form of decreased rates of nosocomial infections, or better outcomes through less frequent complications, also can be used to calculate cost savings to the hospital that could be shared among the participating physicians. Although the success of an infection control and prevention program would be pre-determined by meeting or exceeding certain quality benchmarks for measured parameters, the payment is assessed based on cost savings or cost avoidance calculated by multiplying the number of avoided infections by the published cost of each occurrence of the monitored infection. A cost savings methodology relying on a hospital's "actual acquisition costs," as suggested by CMS, simply is inapplicable here.

With this better understanding of how hospital savings can be determined in the context of quality-focused infection control and prevention programs, IDSA urges CMS to broaden its definition of incentive payment programs to include quality-focused programs where payments for achieving quality measures are based on savings achieved by the hospital as a result of having met those quality benchmarks. This is distinct from other the traditional shared savings programs that are designed primarily to reduce waste through changes in administrative or clinical practice.

II. CMS should expand the list of permitted patient care quality measures to include nationally-recognized data sources and measures that reflect objective, evidence-based quality outcomes or standards.[15]

CMS has proposed that patient care quality measures be those listed in its Specification Manual for National Hospital Quality Measures ("Specification Manual"). IDSA, like other commenters, believes that this is entirely too limiting and does not capture the breadth of nationally-recognized data sources and measures that reflect objective, evidence-based quality outcomes or standards. While IDSA appreciates that the risk of program or patient abuse is

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[14] Daniel P. McQuillen et al., The Value of Infectious Disease Specialists: Non-Patient Care Activities, 47 Clin. Infect. Dis. 1052, 1052 (Oct. 15, 2008) (citing Rebecca R. Roberts et al., The Use of Economic Modeling to Determine the Hospital Costs Associated with Nosocomial Infections and Zhan, 36 Clin. Infect. Dis. 1424-32 (June 1, 2003) and Chunliu Zhan et al., Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization, 290 J. of Amer. Med. Assoc. 1868-74 (Oct. 8, 2003)).

[15] This section generally addresses CMS' solicitation of **Comments #10 and #11** (regarding appropriate quality measures and how CMS might avoid protecting payments based on sham measures or measures that do not reflect objective quality outcomes or standards).

reduced by adherence to objective, independent medical evidence that is published by a nationally-recognized data, CMS must not lose sight of the need to allow enough local flexibility in program design.

A. Additional measures on which hospitals rely.

There are a number of sets of standards and recognized indicia of quality, many of which are not contained in the Specification Manual, on which hospitals already rely to measure patient care. For example, the National Healthcare Safety Network (NHSN,[16] administered by CDC, provides robust data for comparison of hospital infection rates that can be used at the local level to establish a performance improvement baseline for infection control programs. Likewise, the Healthcare Infection Control Practices Advisory Committee ("HICPAC"),[17] also under the auspices of CDC, provides a source of best practices for infection control and prevention, establishing protocols for standardization across the country.

Thus, a hospital could not necessarily point to the Specification Manual as a basis for establishing a program designed to reduce a group of infections including catheter-associated urinary tract infections, post-operative mediastinitis after coronary artery bypass graft surgery, vascular catheter associated infection and post-operative infection after knee replacement surgery. These very conditions are included by CMS in its HAC payment policy.

B. Protecting against sham transactions based on sham measures.

IDSA believes that any protection against "sham" transactions CMS may gain by a narrow reliance on the Specification Manual is far outweighed by the loss of potential innovations, based on other measures, which similarly would improve quality and reduce costs for patients and the program. That said, IDSA proposes that incentive payment and shared savings programs be presumed to be compliant with the exception if they are supported by nationally recognized data sources or measures that reflect objective, evidence-based quality outcomes or standards.

IDSA also suggests that CMS establish a public listing of measures that the agency will affirmatively deem to meet these criteria and allow (through an expansion of the advisory opinion process or otherwise) interested parties to submit measures for consideration under this deeming authority. CMS should establish a process for updating the list of measures regularly. Because the entity submitting a claim already carries the burden of proof that the service was not furnished pursuant to a prohibited referral[18] it is unnecessary — not to mention cumbersome — to attempt to identify each and every valid measure that legitimately may be used either in the regulation itself or through the deeming process.

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[16] http://www.cdc.gov/ncidod/dhqp/nnis.html.
[17] http://www.cdc.gov/ncidod/dhqp/hicpac.html.
[18] *See* 42 C.F.R. § 411.353(c)(2).

C. CMS should allow infection control and prevention benchmarks to be based on local problems as compared to national and regional data.[19]

IDSA supports CMS' proposed condition that the incentive payment or shared savings program establish target levels for the performance measures that are developed by comparing historical data for the hospital's practice and patient population to national or regional data for comparable hospitals' practices and patient populations.[20] IDSA believes it is important to recognize that although evidence-based clinical practice guidelines have been developed by many organizations, including IDSA, implementation of these guidelines must be adapted to the individual hospital. The NHSN database discussed above provides national comparison data for infection rates specific to particular procedures and stratified for hospital size and type. In selecting performance targets, hospitals must carefully consider antibiogram data, drug formularies, and capability and capacity for the individual institution to implement guidelines and adherence protocols. Institutions that are already below NHSN infection rates for particular procedures can use local baseline data collected as part of their own infection control and prevention programs to identify needed areas for further improvement. Only programs that are thoughtfully designed at the individual hospital-level to address quality and efficiency will be successful. Although national measures serve as a critical, and necessary, starting point, the problems or solutions in one institution may be unavailable in another. Thus, IDSA supports CMS' proposal with national or regional standards and quality measures while retaining the flexibility to identify specific targets that reflect the needs and goals of the individual hospital.

III. CMS should allow maximum flexibility in identifying participating physicians by (a) not grouping physicians into payment pools with a minimum number of physicians, (b) allowing multiple physician specialties to participate, and (c) allowing physicians to be added to an ongoing program.[21]

A. Payment pools.

IDSA recommends that CMS not require incentive payment pools with a minimum number of physicians. CMS' proposed "pools" of five or more participating physicians is not realistic for smaller hospitals and certain specialties, such as ID. There are many hospitals in the United States, especially smaller hospitals and hospitals in rural areas that do not have five ID physicians on staff. Many of these hospitals often have only one ID physician on staff. Even many larger hospitals do not have five ID physicians on staff. These circumstances mean that ID physicians are as likely to partner with non-physician providers as with other physicians to implement infection control and prevention procedures.

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[19] This section generally addresses CMS' solicitation of **Comment #42** (regarding how quality improvement should be measured including whether the target should reflect regional data, national data, or some other data).
[20] Proposed 42 C.F.R. § 411.357(x)(3)(ii).
[21] This section generally addresses CMS' solicitation of **Comment #15** (regarding the proposed "five-physician pool" minimum), **Comment #16** (regarding the requirement that all physicians be in the same specialty) and **Comment #18** (regarding whether physician members may be added during an ongoing program).

B. Multiple physician specialties.

IDSA recommends that CMS allow multiple physician specialties to participate in a program. In addition to working with non-physician hospital personnel, the ID physician works with physicians across a range of specialties to implement appropriate infection control and prevention procedures in the inpatient setting. Examples abound of the central but collaborative role of ID physicians in conceptualizing, designing, implementing, and ensuring adherence to these procedures. ID physicians play the leading role in ensuring that hospital staff, including surgeons, radiologists, anesthesiologists, hospital nursing staff, and other, follow foley catheter and central venous catheter maintenance and infection prevention procedures. ID physicians also must lead a broad cross section of hospital medical staff to reduce specific infection rates or to contain disease outbreaks. Appropriate isolation procedures and relatively simple but critically important hand washing procedures are all key components of ID physicians' leadership in this area. Given the examples above, IDSA requests that CMS craft an exception that provides enough flexibility for multiple physician specialties within an institution to participate in an "incentive payment" or "shared savings program."

C. Adding physicians to an ongoing program.

IDSA recommends that CMS allow physicians to be added to an ongoing program. Many quality-enhancing and cost reducing programs, such as infection control and prevention programs, attempt to achieve *global* improvement in the quality of care being provided at the hospital. Such programs necessitate the full participation and commitment of all professionals involved. This makes it imperative that new physician adopt all infection control and prevention procedures and be appropriately incentivized for doing so.

IV. CMS should allow payments for maintenance of effort.[22]

Where physicians have helped the hospitals achieve a quality target, and have been paid a fair market value incentive payment for doing so, the hospital still needs the physicians to continue to undertake those same efforts to maintain that quality achievement. For these reasons, IDSA urges CMS to permit hospitals to make payments to physicians in recognition of the continued effort required to maintain previous gains.

Quality maintenance is always a goal of infection control and prevention programs. In fact, the infection control and prevention community routinely struggles to maintain prior successes. Not surprisingly, areas targeted for intervention typically show improvement but previously made gains may drop off as soon as attention shifts to another area. In addition, infection control and prevention is not static. The ability to maintain low infection rates is continually challenged by changing hospital populations, not to mention changing infections. As such, maintenance of previously achieved gains is clear evidence of continued effort, not simply a reflection of a standard practice. Likewise, an increase in infection rates may be due to slippage in protocol adherence or due to fluctuations in case mix or patient population. In some

[22] This section generally addresses CMS' solicitation of **Comment #24** (regarding restricting physicians from receiving payments for previously achieved cost savings or for meeting quality improvement goals that are, or have become over time, standard practice).

instances, it may be due to the introduction of a new pathogen into the hospital environment and require an entirely new approach and program. What initially may appear to be the erosion of previously achieved gains could in fact be due to a shift in a patient population and/or the pathogens occurring in that population.

Because IDSA recognizes that initially implementing and attaining infection control targets is a greater challenge than continued maintenance of previously attained targets, IDSA does not oppose CMS permitting maintenance payments to be made at a lower rate than payments for the initial efforts.

V. CMS should permit payments to physicians that correlate with their personal efforts and achievement of performance measures where such physicians have additional roles and responsibilities in an incentive payment or shared savings program.[23]

IDSA urges CMS to recognize that the value of a physician's contribution to a hospital's program may be more accurately reflected in results achieved than by an hourly rate. This is especially true for those physicians who have additional roles and responsibilities such as the design, development or administration of an incentive payment or shared savings program that correlates with their personal efforts and reflects the achievement of performance measures.[24] Although other Stark law exceptions (e.g., those for fair market value services[25] or personal services[26]) might be applicable for hospital payments for physician services such as program design, development or administration, IDSA recommends that the elements of any incentive payment and shared savings program exception permit additional payments to be made based on the results achieved for those physician participants who are central to the program.

For example, if each member of a medical staff were eligible for $X, $2X, or $3X incentive payment depending on the quality measure achieved under an infection control and prevention program, the ID physician's proportion of the incentive payment should reflect the time and effort devoted to the design, implementation, oversight and monitoring of the infection control and prevention program that achieved those desired quality goals. Among the specialized services an ID physician might provide to a hospital that has implemented an infection control and prevention program are active prevention of transmission of communicable disease and the management of disease outbreaks among health care workers. In addition to directing the hospital's infection-control programs, ID specialists are called on to analyze antibiotic resistance patterns and interpret their significance relative to antibiotic use, consult

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[23] This section generally addresses CMS' solicitation of **Comment #25** (regarding how a hospital would correlate the achievement of performance measures to a particular physician's personal efforts and, in turn, to the amount of the payment).

[24] IDSA assumes that many hospitals instituting incentive programs will monitor physician participation in order to provide interim feedback on physicians' performance in order to give those physicians the opportunity to take additional steps, as necessary, to meet the quality outcomes the hospital is endeavoring to achieve. Accordingly, IDSA recommends that CMS strongly consider comments that propose methods to facilitate hospitals' ability to match the payment of performance measures to a particular physician's efforts and, in turn, to the amount of payment.

[25] 42 C.F.R. § 411.357(l).

[26] Id. § 411.357(d).

with microbiology staff regarding the appropriate use of laboratory and antibiotic susceptibility tests, recommend (or redesign) appropriate immunization response programs, direct early identification of potential health care work-related outbreaks of infection and generally to champion the implementation of the program. Although many ID physicians contract independently with hospitals to provide infection control and prevention services in exchange for an hourly payment or global fee, such reimbursement modalities do not take into account quality and efficiency improvements for meeting or exceeding certain benchmarks. The ability to receive an additional incentive payment on top of an hourly payment or global fee would reward ID physicians for improved patient outcomes and reduced costs related to their infection control and prevention efforts.

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Infection control and prevention is a crucial element of improving quality and reducing costs. Although one method of "shared saving" and "incentive payments" may be through reducing unnecessary items and services directly related to patient care, a key goal of an infection control and prevention program is to improve quality and reduce costs on a systemwide basis as a result of reduced hospital stays and improved patient outcomes. The risks of incentives to reduce or limit care that are associated with other, more traditional, shared savings programs are absent from these types of programs.

As such, IDSA urges CMS to craft a broad incentive payment and shared savings exception to bring to the hospital-physician relationship the opportunity to move from a passive payer to an active purchaser of high quality and efficient care that CMS has brought to the health care community through various value-based purchasing programs. Doing so will help encourage robust and effective infection control and prevention programs that not only prevent patient morbidity and mortality from infectious complications, but also can save an institution and the overall healthcare system significant resources.

If you have any questions about our comments or need any additional information, please contact Jason A. Scull, IDSA's Program Officer for Clinical Affairs, at 703-299-5146. We look forward to working with CMS as it finalizes this provision.

Sincerely,

Anne Gershon, MD, FIDSA
President, IDSA

cc:
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