Antitrust enforcement policy relating to healthcare

Key words: Antitrust, Federal Trade Commission, healthcare, U.S. Department of Justice.

The U.S. Department of Justice and the Federal Trade Commission, on September 27, 1994, issued “Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust.” This important document supercedes a similar but less comprehensive Statement issued the previous year by two Agencies.

The document covers nine topics, several of which are of direct interest to nurse anesthetists, and will affect the way in which anesthetists and anesthesiologists practice their profession.

Traditionally, nurse anesthetists have invoked the antitrust laws to secure protection from anesthesiologists seeking to eliminate or reduce competition from anesthetists. For this reason, AANA has consistently opposed efforts by physicians and other healthcare providers to exempt themselves from the antitrust laws.

Accordingly, the Statements are a positive development for the anesthetists because the two federal agencies responsible for antitrust law enforcement have committed themselves to traditional antitrust enforcement in the healthcare field. The Statements do not contain any new or radical policies or analytical principles. What is innovative is that the Statements relate only to the healthcare field and explain how the antitrust laws will be applied in a variety of situations, many of which are pertinent to CRNA practice.

Before considering the individual Statements, it is important to understand the format and the terminology used throughout the document.

The Statements furnish healthcare providers with “guidance in the form of ‘antitrust safety zones.’” The various safety zones explain circumstances under which the Agencies will not challenge conduct under the antitrust laws. Conduct not falling within a safety zone is not necessarily suspect. Where competitors fix prices or divide markets, “per se” violations of the antitrust laws occur. Describing a violation as “per se” means that the conduct is prohibited and that no excuses are permitted. The Statements note that “per se” violations will be the subject of vigorous antitrust enforcement.

However, most conduct falling outside the safety zones will be evaluated by the Agencies on a “rule of reason” standard. A “rule of reason” analysis takes into account all relevant factors and subjects them to a traditional antitrust evaluation to determine if the conduct is likely to be procompetitive or anticompetitive.

The Statements explain the analytical framework for the “rule of reason” evaluation, which is divided into four steps. The first step is to determine the relevant product or geographic market. The second step is to determine the competitive impact of the conduct at issue. The third step is to quantify the efficiencies likely to be generated by the activity. The final step is to determine if there are unnecessary collateral agreements which would reduce competition. The ultimate favorable or unfavorable evaluation by the Agencies is derived from this four-step analysis.
The Statements renew the commitment by the Agencies to comment on proposed conduct, not involving hospital mergers outside the applicable safety zone or multiprovider networks, within 90 days "after all necessary information is received." Statements Eight and Nine are discussed first, because of their importance to AANA.

Statement Eight—Physician network joint ventures

Statement Eight deals with physician network joint ventures such as individual practice associations (IPAS) and preferred provider organizations (PPOS). The hallmark of such organizations is physician control and collective agreement on the prices to be charged for the marketed services.

Statement Eight grants a safety zone for exclusive physician network joint ventures "comprising 20 percent or less of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market, and share substantial risk."

The relevant geographic market, according to the Statement, is usually a local market such as a city or rural county. Accordingly, in small communities with fewer than five physicians in particular specialties, an otherwise complying physician network joint venture may include one physician from each specialty on a nonexclusive basis.

Nonexclusive physician network joint ventures, by contrast, may comprise 30 percent or fewer of each physician specialty with active hospital staff privileges, who practice in the relevant geographic market and who share substantial financial risk.

The concept of sharing substantial risk is central to the analysis of both physician and multiprovider networks. The sharing can be accomplished by the venture agreeing to provide services at a capitated rate, or by providing substantial financial incentives to achieve cost-containment goals such as withholding a substantial amount of compensation unless and until the cost-containment goals are achieved.

The Statements contemplate that the sharing of substantial financial risk can be achieved by other means, but what they might be is not specified.

Physician network joint ventures not falling within a safety zone are evaluated, as noted above, on a "rule of reason" basis. The principal objective of this analysis is to determine if the venture "could raise the price for physician services charged to health benefit plans above competitive levels, or prevent the formation of other physician network joint ventures that would compete with it."

Physician nonexclusive network joint ventures with high percentages of physician specialties in the relevant geographic market may pass "rule of reason" scrutiny. This is particularly true in the case of small communities, for example, with a population of 25,000 or less, within 35 miles of a large city. In such markets, two of the three obstetricians in the community could be included in a nonexclusive venture, even though constituting 67% of the obstetricians.

A principal criticism of the physician network joint venture section is that it applies exclusively to physicians. A physician network that decided to include nurse anesthetists could not qualify for a safety zone under Statement Eight and would be evaluated under Statement Nine which deals with multiprovider networks.

Statement Nine—Multiprovider networks

As the name implies, multiprovider networks can include both healthcare providers who would otherwise compete with each other, as well as those providing complementary services. Such networks can take a variety of forms. Typically they jointly market their services to health plans and others.

Because such networks are relatively new, the Agencies concluded that they lacked sufficient experience with multiprovider networks to grant any safety zones with respect to them. Consequently the Statement sets forth the analytical principles that will be used to evaluate a multiprovider network's likely effect on competition.

As noted above, the antitrust laws preclude competitors from entering into agreements to allocate markets or to fix prices. Multiprovider joint ventures that intend to set the prices at which their services will be offered must establish that they are an integrated entity. For example, if one-third of the competing healthcare providers in a given community formed the "ABC Network" only to jointly market their services at specified uniform prices, this would constitute a "per se" violation of the antitrust laws, because the essence of the agreement between the competitors would be to fix prices.

However, if the competitors formed a new integrated entity in which the participants shared substantial financial risk, the joint venture network would be evaluated on a "rule of reason" basis. Again, as with the physician networks, the Agencies have announced that the requisite integration and risk sharing can be established by the venture agreeing to provide services to health benefit plans at a capitated rate, or the withholding of substantial compensation from providers to insure that cost-containment goals are achieved.
If the network is sufficiently "integrated," the Agencies would analyze the potential effect it would have on competition between competing providers and on sellers and buyers who are not competitors. A unifying principle of such an evaluation is to determine if the multiprovider network market share could permit it to "increase the price of such services in the market." An important aspect of this evaluation is the ability and willingness of third-party purchasers to switch to different provider networks in response to price increases.

If the providers chose to offer their services exclusively through the network, they will be subject to increased scrutiny to determine whether the arrangement might impede or preclude competition among networks and providers, and if the exclusivity provisions are necessary for the network to function properly.

Another factor the Agencies will consider is whether the network has sufficient size or provider participation, so that the creating of competing networks would be unduly difficult.

The other seven Statements also deserve mention.

Statement One—Mergers of small hospitals
Statement One provides a safety zone for mergers of small hospitals, over five years old, with fewer than 100 licensed beds, and an average daily inpatient census of fewer than 40 patients over the most recent three years. As is the case with all safety zones, if there are "extraordinary circumstances," the safety zone may not apply.

Mergers outside the safety zone are not necessarily anticompetitive. The Statement notes that challenges to hospital mergers are rare.

Statement Two—Hospital joint ventures involving high technology or other expensive healthcare equipment
This Statement grants a safety zone for hospital joint ventures to purchase new or existing highly technology or expensive healthcare equipment "if the joint venture includes only the number of hospitals whose participation is needed to support the equipment." The inclusion in the joint venture of a hospital which could purchase the equipment on its own would preclude reliance on the safety zone.

The safety zone applies only to the joint purchase and use of the equipment and not to collateral subjects such as hospital charges to patients.

Joint ventures falling outside the safety zone will be subject to a "rule of reason" analysis.

Statement Three—Hospital joint ventures involving specialized clinical or other expensive healthcare services
No safety zones are granted for hospital joint ventures involving specialized clinical or other expensive healthcare services, because the Agencies concluded that they lacked sufficient expertise in evaluating such transactions.

Such joint ventures will generally be analyzed on a "rule of reason" basis. One example provided gives a good indication of what will not be found objectionable:

Two hospitals in a rural town of 75,000 population propose a joint venture to recruit a team to establish an open heart surgery program, which neither hospital could support on its own. The program, located in one hospital, will have patient referrals from both. The hospitals will share expenses and revenue, but will not exchange "competitively sensitive information."

Statement Four—The collective provision of nonfee-related information by providers to purchasers of healthcare services
This Statement concerns the collective furnishing of nonfee-related information to purchasers by competing healthcare providers. A safety zone is granted to such activity as a medical society collecting and disseminating outcome data for a procedure they believe should be utilized. Additionally, the Agencies will not challenge, absent extraordinary circumstances, "providers development of suggested practice parameters—standards for patient management developed to assist providers in clinical decision making." In the course of providing the underlying medical data, providers may engage in discussions with purchasers about the scientific merit of the data. However, providers who collectively threaten purchasers "or refuse to deal with them because of objections to their administrative, clinical, or other terms governing the provision of services run a substantial antitrust risk."

Statement Five—Providers collective provision of fee-related information to purchasers of healthcare services
Statement Five grants a safety zone for the collective provision of current or historical fee information by providers to purchasers of healthcare services, if specified procedures are adhered to.

The type of fee-related information covered by the Statement includes fees, other aspects of reimbursement, discounts, and alternative reimbursement methods such as capitated rates and risk-withhold fee arrangements.

In order to qualify for the safety zone, the following three conditions must be satisfied:
1. The collection of the information must be managed by a third party such as a purchaser, an academic institution, or a trade association.

2. The fee-related information is more than three months old.

3. Each reported statistic must reflect data from not less than five providers; no one provider may represent more than 25% on a weighted basis of the reported statistic; and prices charged by any given provider could not be identified.

In the Statement, the Agencies warn providers that the safety zone does not extend to collective fee negotiations between unintegrated providers and purchasers. Nor does the safety zone extend to agreements by unintegrated providers to deal with purchasers only on agreed terms.

The Agencies also caution that providers “may not collectively threaten, implicitly or explicitly, to engage in a boycott or similar conduct, or actually undertake such a boycott or conduct to coerce any purchaser to accept collectively determined fees or other terms or aspects of reimbursements.” Indeed, as the Statement notes, such conduct might be regarded as per se illegal.

The Statement also contains a warning about the dangers of providing fee-related information. Prospective fee-related information has no safety zone, and though evaluated on a “rule of reason” basis, can be subject to abuse and may lead to charges of unlawful collective negotiations and agreements as to price between competitors.

Statement Six—Provider participation in the exchange of price and cost information

This Statement provides a safety zone for provider participation in written surveys of (a) prices for healthcare services, or (b) wages, salaries, or benefits of healthcare personnel if three conditions are satisfied:

1. The survey is managed by a third party.
2. The information provided is more than three months old.
3. At least five providers submit data; no individual provider’s data represents more than 25% of the data on a weighted basis; and prices charged or compensation paid by particular providers cannot be identified.

Exchanges of information falling outside the safety zone will be tested on a “rule of reason” standard. The Agencies favor nonprovider initiated surveys and caution that exchanges of future prices or future rates of compensation “are very likely to be considered anticompetitive.” If the exchange of information leads to an agreement among competitors as to prices for healthcare services or compensation to healthcare employees, the participating parties will have committed a per se violation of the antitrust laws.

Statement Seven—Joint purchasing arrangements among healthcare providers

This Statement deals with joint purchasing arrangements among hospitals and other healthcare providers to secure products and services, such as laundry, food services, data processing, and pharmaceutical products.

The Agencies note that joint purchasing is not apt to raise antitrust concerns unless (1) the arrangements account for so large a portion of the purchases of a product or service that it can effectively exercise market power in the purchase of the product or service, or (2) the products or services being purchased jointly account for so large a proportion of the total cost of the services being sold by the participants that the joint purchasing arrangement may facilitate price fixing.

The Statement grants a safety zone where two conditions are present: (1) the purchases account for less than 35 percent of the total sales of the purchased product in the relevant market, and (2) the cost of the products and services purchased jointly account for less than 20 percent of the total revenues from all products or services sold by each competing participant.

The rationale for the two conditions is that the limitations imposed would preclude buyers from driving down prices below competitive levels and that joint purchasing would lead to fixed uniform prices charged to consumers.

Joint purchasing arrangements falling outside the safety zone do not necessarily raise antitrust concerns. The Statement discusses steps that participants can take to reduce antitrust risk. These include permitting participants to purchase less than their total needs for the products or services from sources other than the joint venture.

Having the purchasing arrangements negotiated by an independent employee, one not employed by any of the joint venturers, also lowers antitrust risk. Additionally, keeping confidential the communication between the purchasing group and the joint venturers reduces the risk that anticompetitive communication will take place.

It will of course be necessary to monitor closely the way that the Statements are administered by the Agencies. There is a danger that the Statements will be utilized by healthcare providers to justify restrictions on practice by nonphysician healthcare providers. Any such conduct should promptly be brought to the attention of the Agencies.
FROM REGULATION TO RESPONSE IN SECONDS

Suprane®

desflurane

Inhalation Anesthetic for Maintenance

*Changes in the clinical effects of Suprane® rapidly follow changes in the inspired concentration. Please see brief summary of Prescribing Information that follows.
SUPRANE® (desflurane) provides faster alteration of anesthetic depth

- The lowest solubility of all potent inhalation agents

  —permits faster wash-in and wash-out than isoflurane...provides better control with lower flow rates...speeds the alteration of anesthetic depth with lower MAC multiples...provides the option of eliminating N₂O from technique

- More rapid adjustment to unexpected hemodynamic responses and anticipated surgical stimuli versus isoflurane

- Precise control over anesthetic depth can be achieved more readily with SUPRANE® than with isoflurane or propofol

Note: SUPRANE® is not recommended for induction of general anesthesia in infants or children because of the high incidence of moderate-to-severe laryngospasm, coughing, breath holding, and secretions. SUPRANE® should not be used as the sole agent for anesthetic induction in patients with coronary artery disease or patients where increases in heart rate or blood pressure are undesirable. During induction in such patients, SUPRANE® should be used with other medications, preferably intravenous opioids and hypnotics. Please see brief summary of Prescribing Information that follows.
...THE RECOVERY YOU WANT

Suprane® enhances the quality of recovery
- Suprane® patients emerge nearly twice as fast as isoflurane patients (time to eyes opening)\textsuperscript{10}
- Suprane® patients recover cognitive function faster than isoflurane\textsuperscript{10,11} or propofol\textsuperscript{12} patients

Suprane® provides cost-effective control
- Used at lower flow rates, Suprane® costs the same or less than isoflurane\textsuperscript{13,14} and significantly less than propofol in clinical usage\textsuperscript{15}
- Faster emergence and faster recovery with Suprane® may lead to increased OR turnover, less nursing staff intervention, earlier discharge from PACU\textsuperscript{16}

Suprane® desflurane
ADVANCES CONTROL...CONTROLS COSTS.
Suprane® (desflurane) Volatile liquid for inhalation.

The following is a brief summary. Please see complete prescribing information before prescribing.

INDICATIONS AND USAGE
Suprane® (desflurane) is indicated as an inhalation agent for induction and/or maintenance of anesthesia for infratentorial and outpatientsurgery in adults (see PRECAUTIONS).

CONTRAINDICATIONS
Suprane® (desflurane) should not be used in patients with known or suspected genetic susceptibility to malignant hyperthermia.

WARNINGS
Pediatric use: Suprane® (desflurane) is not recommended for induction of general anesthesia via mask in infants or children as there is no evidence of adequate performance or safety in this age group. However, in infants or children over the age of 1 month, Suprane® may be used for maintenance of anesthesia in association with endotracheal intubation by an experienced anesthesiologist and in the presence of adequate personnel trained in the management of respiratory failure (see CLINICAL STUDIES).

PRECAUTIONS
During the maintenance of anesthesia, increasing concentrations of Suprane® (desflurane) produce dose-dependent decreases in blood pressure. Therefore, in patients in whom cardiovascular disease or pre-existing arterial disease is present, the dose of Suprane® should be reduced when indicated. The recovery from general anesthesia should be assessed carefully before patients are discharged from the anesthetic care unit (PACU).

Drug Interactions
No clinically significant adverse interactions with commonly used preanesthetic drugs, or drugs used during induction of anesthesia, such as local anesthetics, have been observed in clinical trials. The effect of desflurane on the disposition of other drugs has not been determined.

NERVOUS SYSTEM BLOCKING AGENTS
Anesthetic concentrations of desflurane at equilibrium (administered for 15 or more minutes before testing) reduced the ED50 of succinylcholine by approximately 30% and that of atracurium and vecuronium by approximately 50% compared to the effect of 1.25 MAC 60% isoflurane (N=30) undergoing renal transplant.

Dosage reduction of neuromuscular blocking agents during induction of anesthesia may result in delayed onset of conditions suitable for endotracheal intubation or inadequate muscle relaxation, because potentiation of neuromuscular blocking agents requires equilibration of muscle with the delivered partial pressure of desflurane. Appropriate measures should be taken to maintain cerebral perfusion pressure (see CLINICAL STUDIES, Neuromuscular System).

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DOSAGE OF MUSCLE RELAXANT CAUSING 90% DEPRESSION IN NEUROMUSCULAR BLOCKADE

Eight patients receiving Suprane® (desflurane) were compared to six patients receiving isoflurane, all with normal renal function (serum creatinine 0.5-1.5 mg/dL) and no evidence of hematological or biochemical tests, including hepatic enzymes and hepatic function evaluation, were seen. The predicted effects of acute overdosage by inhalation of Suprane® (desflurane) include headache, dizziness or (in extreme cases) unconsciousness. The predicted effects of acute overdosage by inhalation of Suprane® (desflurane) include headache, dizziness or (in extreme cases) unconsciousness. The predicted effects of acute overdosage by inhalation of Suprane® (desflurane) include headache, dizziness or (in extreme cases) unconsciousness.

Malignant Hyperthermia
A number of studies have been performed with Suprane® (desflurane). In vitro and in vivo genotoxicity studies did not demonstrate genotoxicity or chromosomal damage by Suprane® (desflurane). Toxicological studies included inhalation and intravenous injection of Suprane® (desflurane), the metabolic analysis, the analysis of human lymphocytes, and the mouse microscopic assay.

Malignant hyperthermia is a potentially fatal genetic disease characterized by a rapid, uncontrolled increase in muscle temperature which is precipitated by the use of muscle relaxant drugs, especially succinylcholine. In the event of overtreatment, or suspected overtreatment, take the following actions: discontinue administration of SUPRANE® (desflurane), maintain a patent airway, initiate assisted or controlled ventilation with 100% oxygen and hyperventilation (hypocapnia) until cerebral decompression in patients with known or suspected malignant hyperthermia is confirmed. In the event of overtreatment, or suspected overtreatment, take the following actions: discontinue administration of SUPRANE® (desflurane), maintain a patent airway, initiate assisted or controlled ventilation with 100% oxygen and hyperventilation (hypocapnia) until cerebral decompression in patients with known or suspected malignant hyperthermia is confirmed.

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