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Legislative Update

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ASC Program Transmittal

The latest word from HCFA is that the ASC final rule will not be published until at least November 2000, and will carry an implementation date of spring 2001. This is a significant delay over HCFA's previous estimates. The revised time frame is a result of the difficulty HCFA is experiencing in complying with the ASC provisions of the BBRA which requires the agency to phase-in the APC system's new ASC rates over a period of at least three years, if HCFA fails to incorporate data from its 1999 Medicare ASC survey into the forthcoming rule. We understand from sources at HCFA that data from the 1999 Medicare survey will not be available for quite some time. Thus, HCFA must either wait until the survey is complete and the resulting data has been incorporated in the APC payment system, or HCFA must create an appropriate phase-in mechanism.

In the interim, due in large part to the efforts of AOPMA, HCFA released a Program Memorandum (transmittal number AB-00-28) adding some of the replacement codes deleted by the January 1, 2000 update of the CPT Manual by the American Medical Association to the ASC approved procedures list. Carriers and intermediaries were instructed to apply the new payment policy to claims with a date of service on or after January 1, 2000. Although HCFA restored funding for a series of pain management procedures, it did not provide ambulatory surgical center facility reimbursement for a number of other 2000 CPT codes: 62263, 64479, 64480, 64483, 64484, 64470, 64470, 64472, 64626, and 64627.

AOPMA is working vigorously with HCFA to address this oversight. In addition, AOPMA's Washington representatives have been and continue to meet with individual members of the House of Representatives and Senate requesting their attention to this matter.

Hospital Outpatient Final Rule Released

As expected, the Hospital Outpatient Department (HOPD) PPS final rule was published in the *Federal Register* on April 7. This new prospective payment system for HOPD services will become effective as of August 1, 2000 unless industry groups successfully argue for another extension. Certain components of the rule reflect recently enacted requirements of the Balanced Budget Refinement Act of 1999 (BBRA), and therefore, were not included in HCFA's initial proposed rule. As a result, HCFA accepted comments on these issues regarding the final rule until June 6th.

According to HCFA, the payment rates for HOPD services finalized in this PPS rule reflect a 10% overall increase in payment over the amounts contained in the original proposed rule. Due to AOPMA's lobbying efforts, payments for nearly every service and procedure important to pain management specialists were increased under the final rule. In general, HCFA expects payments for HOPD services to rise nearly $1.1 billion in fiscal year 2000 under this new system, although in the long term the PPS system is expected to reduce HOPD payments through increased efficiencies.

Several hospital organizations have voiced serious concerns regarding whether the HOPD PPS system will be ready on time. The Catholic Healthcare Partners Network (a network of thirty hospitals in Kentucky, Ohio, Pennsylvania, and Tennessee) has launched a lobbying campaign to convince Congress to force HCFA to delay implementation of the HOPD PPS system for at least six months. The health system claims this delay is necessary for hospitals to have enough time to implement the systems and software necessary to comply with the new rule. In addition, in a May 15 letter to HCFA, four hospital groups said they are concerned about efforts to train fis-

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cal intermediaries and hospitals about the new payment system. They are calling on HCFA to pre-pay PPS claims during June, and beyond. Doing so, they claim, would allow hospitals to continue being paid for delivering outpatient services if problems develop with the PPS.

After careful consideration of the status of the systems changes at its contractors and around the country to implement the PPS system, HCFA announced June 6th that it will delay implementation of the PPS until August 1, 2000. Claims received for outpatient services rendered on or after August 1st will be paid under the PPS . Claims received for outpatient services provided before August 1st will be paid under current rules. In addition, HCFA announced a plan to begin working with hospitals in July to inform beneficiaries that the changes related to the PPS could mean changes in their coinsurance responsibilities.

Draft Compliance Program Guidance for Physician Practices

On June 7, 2000, the OIG released a draft compliance program guidance for individual and small group physician practices. The document may be obtained from the OIG homepage at http://www.dhhs.gov/proorg/oig/modcomp/cpgphysiciandraft.htm. It will be published in the Federal Register later this month and will have a forty-five (45) day comment period. As expected, the draft guidance requires that the seven basic elements included in each of the model compliance programs developed previously for other providers such as hospitals, home health care agencies, and third-party billing companies, be included in a physician practice complaince plan. These elements include: written policies and procedures, designations of a compliance officer, institution of compliance training and education including billing and coding training, development of lines of communication, ongoing auditing and monitoring systems, enforcement and discipline guidelines, and a corrective action plan.

The guidance recognizes that the areas of greatest fraud and abuse concern for physician practices and thus, a focus of the compliance program, are establishment that a service is reasonable and necessary, physician relationships with hospitals, physician billing practices, unlawful advertising, and lease arrangements for office space with referral sources. Realizing the importance of compliance programs for pain management specialists, AOPMA engaged the law firm of Arent Fox this past year to develop a model compliance program for pain management practices. This model program is available by contacting the Association of Pain Management Anesthesiologists, 2831 Lone Oak Rd., Paducah, KY, 42003, or order on-line at their website: www.aopma.org

Humana Agrees to Pay $14.5 Million

In the first settlement between the Department of Justice and a managed care plan, Humana agreed to pay $14.5 million to settle claims that it submitted false information to the Medicare program in order to increase the fixed monthly payments it received from the program. Under the Medicare program, managed care plans receive fixed monthly payments to provide health care services for Medicare beneficiaries. These payments are increased for beneficiaries who are eligible for both Medicare and Medicaid or dual eligible beneficiaries. According to the Government, Humana submitted false records to inflate its reimbursement from Medicare.

As part of the settlement terms, Humana agreed to enter into a comprehensive five-year corporate integrity agreement ("CIA") with the OIG. CIAs are comparable to a highly detailed compliance program imposed on a provider by the OIG. Among other things, the CIA requires Humana to provide compliance training to its employees, to undergo independent audits yearly, and to submit annual compliance reports tot he OIG.

Stark Law Final Regulations

The latest information from HCFA is that the Agency is working feverishly to complete the rule for publication in the upcoming weeks. The target date is in July.

Patient's Bill of Rights

With the Memorial Day recess, the House-Senate conference committee assigned to merge the House (H.R. 2990) and Senate (S. 1344) managed care reform bills appeared to have made little progress toward resolving outstanding issues. Conferees reportedly spent most of a May 25 session discussing liability – particularly the degree to which employers should be held accountable if they make medical decisions. While it became increasingly clear that a deal was unlikely to be reached before the recess, Charles Norwood (R-CA), who sponsored the House passed-bill, but was not appointed to the conference committee, threatened to pursue avenues outside the mired House-Senate conference in order to get a bill passed this year.

Prior to the spring recess, the conferees reached agreement on several of the less controversial issues and a subgroup was tasked with the job of negotiating the basic elements of an external appeals process for patients who receive adverse health claim determinations. The subgroup, led by Conference Chairman Senator Don Nickles (R-OK), agreed that aggrieved patients who have exhausted their health plan's internal review process may appeal to an external reviewer, which would be chosen by an independent review entity that contracts with a health plan.

Under a tentative agreement, patients would have access to external review if the cost of the sought treatment exceeded a "significant financial threshold," or if their life or health were in danger. Patients would pay a $50 appeal-filing fee, which would be refunded if the claimant prevailed, and waived for low-income patients. The appeal provision stipulates three major conditions under which a patient would have access to the external review mechanism:

- the plan determines that there is a lack of medical necessity or appropriateness;
- the plan determines that the treatment is experimental or investigational; or
- the plan denied the claim because it did not deem the treatment to be covered under its terms.

The medical reviewer would examine the information provided by the plan, patient, and patient's physician and make an independent determination based on the medical condition of the patient and consistent with the valid, relevant scientific and clinical evidence. The subgroup did not reach agreement, however, as to whether the federal procedure for choosing an independent external reviewer will preempt existing laws in over thirty states already mandating such procedures.

The Conferees still have yet to tackle the divisive area of scope of coverage, in addition to other issues including the tax and health insurance access provisions.

Pain Relief Promotion Act

Just two days after the April 25th Senate Judiciary Committee hearing concerning the Pain Relief Promotion Act, where Sen. Gordon Smith (R-Ore.), one of the co-authors of the 1994 Oregon law legalizing physician-assisted suicide, dropped his opposition to the bill the Committee approved a substitute version of H.R. 2260, S. 1272, by a 10 to 7 vote. According to Smith, he changed his position after amendments to the bill were made to guarantee that physicians would have the freedom to treat patients for pain without fear of federal prosecution.

The approval came despite an emotional appeal by Sen. Dianne Feinstein (D-CA) to reject the substitute on the grounds that it will add to an epidemic of under-treatment of pain associated with cancer and other diseases. In opposing the bill, Feinstein predicted the Act, including the Hatch substitute, will backfire because it will make physicians even more fearful that they will be prosecuted if they use the powerful doses required to treat pain aggressively. Sen. Orin Hatch (R-UT) said the substitute "clearly and unambiguously" states that pain management activities are protected from prosecution and requires a higher standard of evidence the government must meet to prove a physician intended to assist a suicide.

Sustainable Growth Rate of 5.8%

By final notice published April 10th, HCFA announced that the sustainable growth rate ("SGR") for fiscal year 2000 is approximately 5.8 percent. The SGR is used to control growth in the Medicare program related to spending for physician services. It does not, however, limit expenditures. Rather if expenditures exceed the SGR, the update is reduced, and increased if expenditures are less than the expected target. According to the *Federal Register* notice, the 2000 rate is a composition of four values: a 2.1 percent increase in fees for physician services, a 0.6 percent decrease in beneficiary enrollment, a 2.5 percent increase based on the GDP, and a 1.7 percent increase mandated by statute.

Lawsuit Challenging HHS Decision Dismissed

The lawsuit filed by the American Society of Anesthesiologists and four other medical societies challenging the Department of Health Human Services decision that Medicare will not cover costs incurred by physicians when members of their office staff accompany them in the hospital setting was dismissed March 31st on jurisdictional grounds. The plaintiffs were asking for an order preventing HCFA from implementing the resource-based physician fee schedule because the methodology to calculate practice expense excluded costs incurred when physicians' staff assist in the hospital setting. No decision whether to appeal has been made.

Reprocessing of Single-Use Devices

The Food and Drug Administration recently issued draft guidance outlining a comprehensive scheme to regulate hospitals that reprocess and reuse medical devices labeled as disposable or "single-use only" such as endoscopes, catheters, or keratome blades. Under the FDA's proposed scheme, hospitals that engage in reprocessing would be subject to the same regulatory requirements as medical device manufacturers including: registration and listing; medical device reporting, tracking, and corrections and removals; quality system regulations; labeling; and premarket requirements. The guidance comes in the wake of charges by Congress and the medical device industry that reprocessing may affect device performance, and that reuse may lead to disease transmission if the cleaning or sterilization is inadequate. Currently, the guidance applies only to hospitals, however the Agency is evaluating whether to extend the requirements to physician offices and nursing homes as well as other settings.

Exclusive Credentialing

According to Chief Counsel, Mac Thorton, the OIG is considering issuing a Special Fraud Alert this year on exclusive credentialing. Under this practice, physicians must agree to refer all or most of their patients to a particular hospital in order to be granted the right to practice at the facility. In some instances, according to the AMA, physicians must also agree not to compete with the hospital such as by opening an ASC nearby or admitting patients to another hospital.

Exclusive Contracting for Anesthesia Services

On April 3, 2000 the Eighth Circuit Court ruled that an exclusive dealing arrangement between three hospitals and two anesthesia groups in Minnesota does not rise to a group boycott in violation of section 1 of the Sherman Antitrust Act. Section 1 makes unlawful, among other things, contracts, combinations, and conspiracies in restraint of trade.

At issue in the case, Minnesota Association of Nurse Anesthetists v. Unity Hospital, was a sole-sourcing arrangement whereby three Minnesota hospitals decided to sole-source their anesthesia services. In doing so, the hospitals terminated the employment contracts of their staff nurse anesthetists and entered into exclusive dealing contracts with two physician anesthesiology groups for the provision of all anesthesia services at the institutions. The contracts required the anesthesiologists to provide the hospitals with nurse anesthetist services. According to the plaintiffs, however, the contracts amounted to a conspiracy by anesthesiologists in the state to eliminate nurse anesthetists as a class of competitors.

In the court's opinion, the plaintiffs' allegations were without legal or factual merit. As a legal matter, the court stated that it is not necessarily an antitrust boycott simply because one supplier enters into an exclusive arrangement with one customer even though the supplier's competitors may be foreclosed from providing services to that customer during the term of the contract. Of significance to the court's conclusion, was that the defendants did not possess sufficient market power, nor did their acts cause actual detrimental anti-competitive effects in the relevant market such that the exclusive dealing arrangements failed an antitrust analysis. Furthermore, as a factual matter, neither party to the exclusive contract stopped dealing with nurse anesthetists.

Physician Financial Incentives

On April 11, 2000, the Texas Attorney General's office announced a settlement in a lawsuit originally filed against Aetna U.S. Healthcare, Inc. and five other health maintenance organizations alleging that the HMOs illegally compensated physicians who limited medical services to plan enrollees and penalized those physicians who did not. Health attorneys are predicting that the Aetna deal in Texas may goad other state officials into either beginning or stepping up existing probes of managed care practices within their borders. Officials at Aetna are looking into whether similar out-of-court settlements can be applied to other states and markets.

Under the agreement, which applies only to Aetna and Prudential, the methods of capitation and other financial incentive arrangements Aetna may use in its contracts with providers are restricted. The Attorney General currently is seeking compliance with the agreement reached with Aetna by the other four named defendants: Humana Health Plan of Texas, Inc, PacifiCare of Texas, Inc., NYLCare Health Plans of Southwest, and NYLCare Health Plans of the Gulf Coast.

Highlights of the settlement include agreements by Aetna to refrain from using financial bonuses in contracts with primary care physicians for not exceeding certain budget targets, or penalizing physicians for medically necessary expenses. In contracts with risk-bearing provider net-

works, Aetna agreed not to use financial incentives unless there is some type of stop-loss insurance or other protection available to minimize any inducement to limit services to plan members. The entire settlement agreement may be accessed on the Texas Attorney General homepage at: http://www.oag.state.tx.us/newspubs/releases/2000/20000411aetna.htm.

HHS Spending Bill for Fiscal Year 2001

On May 11, the Senate Appropriations Committee approved the FY 2001 spending bill for the Department of Health and Human Services (HHS). The spending levels largely mirror the figures passed by the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education. According to committee information dated May 10, spending for the Health Care Financing Administration will total $202.2 billion, compared to the $189 billion HHS received in FY 2000. The National Institutes of Health would receive $20.5 billion, an increase of $2.7 billion from FY 2000 levels. The Centers for Disease Control and Prevention would receive $3.2 billion, compared to the $3 billion received in FY 2000.

President Clinton criticized the bills passed by the House and Senate Labor-HHS subcommittees for failing to support key health programs by reducing funding for mental health and family planning services and substance abuse programs. The President also expressed disapproval of the House subcommittee's decision to cut Medicare survey and certificate activities, which are used to monitor nursing home quality.

Medicare Coverage Decisions

In attempting to end a decade-long controversy over its coverage process, HCFA unveiled proposed national standards it will use in making decisions regarding medical device and services coverage. In a notice of intent to publish the proposed rule, HCFA explained it would use a multi-step process to determine whether a medical device or service should be covered by Medicare. The Agency said it is considering using a cost-effectiveness analysis – a highly controversial procedure opposed by health industry manufacturers.

A cost-effectiveness methodology would determine if medical devices and services meet two criteria: whether they demonstrate medical benefit and whether they provide added value to the program. The Agency explained that cost would not be considered in making a coverage decision if an item or service would be medically beneficial and there is no alternative treatment available. However, health industry manufacturers have maintained that cost-effectiveness is an inexact science and have questioned how data would be gathered and how HCFA would use the information.

In recognition of the sensitivity of the issue, HCFA has added an extra step in the rulemaking process and will take comments on its proposed guidelines for 30 days. Then the agency will issue a proposed rule that will be subject to the normal comment and review process before a final rule is issued. HCFA issued the notice of intent to publish a proposed rule on May 16, 2000, with comment period ending June 15, 2000.

Pediatrician Wins Exclusive Contract

Los Angeles pediatrician, Pejman Salimpour, MD, wanted to ensure that the neonatologists in his practice could treat patients at a Southern California hospital that had closed its neonatal intensive care staff. Dr. Salimpour's efforts resulted in a declaration from two state regulators and a judge that exclusive contracts outside the hospital-based practices of pathology, radiology and anesthesiology are illegal in California hospitals that accept state funds. In addition, Providence Saint Joseph Medical Center, the hospital that had refused to allow Dr. Salimpour's neonatologists to see patients, reversed its position and opened the staffs of its neonatal intensive care and cardiac surgery units. Dr. Salimpour said he hopes his own success will serve as an example to other physicians and encourage them to challenge exclusive contracts.

Medicare Errors

Recently, lawmakers, health care groups, as well as physicians have begun to seek concrete mechanisms to reduce medical errors. The Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act of 2000 was introduced in Congress in April. The SAFE bill has bipartisan support and would require safety programs by hospitals, ambulatory surgery centers, and other facilities as a condition of participation in Medicare and Medicaid. The bill also would establish a federal safety center and expand peer review protections to error reports and analyses. In addition, a number of private-sector organizations, including the National Patient Safety Foundation and Kaiser Permanente, are attempting to implement error-reduction strategies.

In response, physicians are being urged to take a few simple steps to help reduce medical errors on their own. At a recent forum sponsored by the AMA, physicians were encouraged to develop checklists and protocols for handling highly hazardous procedures or medications. In addition, practice guidelines could be more widely disseminated and used and teams of physicians and other caregivers, working together in hospital settings, could take stock of potential dangers in the processes they follow and devise solutions before errors occur.

Physician Collective Bargaining

Despite strong support from the physician community, including the AMA, the future of the Quality Health-Care Coalition Act of 1999 (H.R. 1304) is dubious. The bill, introduced by Tom Campbell (R-CA) and co-sponsored by 223 members of Congress, would grant independent/self-employed physicians an exception from the Federal antitrust laws in order to organize for the purposes of bargaining collectively with health plans.

On May 25, the House Rules Committee removed the bill from the floor vote schedule. Campbell blamed the delay on fellow Republicans who he claims did not want to be forced to choose between two highly sought after campaign contributors, health insurers and medicine. The bill has been strongly opposed by hospitals, health plans, employers, as well as the Federal trade commission. The bill may be rescheduled for floor vote in the upcoming weeks.