PACIFIC RIM ADVISORY COUNCIL

APRIL e-BULLETIN

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MEMBERSHIP Events
- May 2 @ 3:30 pm PRAC @ INTA – Members Gathering -Atlanta Marriott Marquis - Champions Lounge (contact Moira Huggard-Caine / Tozzini for details (mhuggardcaine@tozzini.com.br)
- May 15-21 Peru 2004 Conference - Advance Conference Materials **NOW AVAILABLE @ web site**
- October 30 – November 5 New Delhi/Agra 2004 Conference - Details shortly

Tools to Use
- PRAC Contacts Matrix & Email Listing - April Update (member version only) 15
- PDF version Directory 2003-2004 Member Firms **available** at PRAC web site
- Expert System 2003 available at PRAC web site Private Libraries

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Visit the PRAC web site www.prac.org to view this edition and other information on line

ALLENDE & BREA ASSOCIATE ANNOUNCEMENT

We want to annunciate that we have appointed Julián Peña as an associate starting today. Mr. Peña has vast experience both in antitrust as well as trade issues given his past positions in the public sector. Julián has worked at the Ministry of Economy for the past eight years. During that time, he was legal adviser to different Ministers and Secretaries of Trade and Industry, as well as being on the staff of the Comisión Nacional de Defensa de la Competencia (Argentina´s Competition authority) between 1999 and 2001. Before joining the Ministry of Economy in 1996, Mr. Peña worked at the European Commission in Brussels, and has studied in the United States and Spain.

Julián Peña is also deeply committed to trade and competition issues. Currently he is Professor of Competition Law at the graduate program of the Universidad de Buenos Aires Law School. He published a book on merger control (*Control de Concentraciones Económicas. Marco normativo e interpretación jurisprudencial,* Rubinzal Culzoni, 2002*)* and has also published numerous articles on competition law, integration law and electronic commerce in different national and foreign legal journals. He has also been invited to give conferences on these issues.

Mr. Peña is also the founder and moderator of *ForoCompetencia*, an e-group on competition issues composed of 300 economists and lawyers from the public, private and academic sectors of 20 countries in Europe and America. This group has virtual debates every month on different competition-related topics and organized an important international symposium in Buenos Aires in October last year, featuring experts on competition from seven countries.

We shall regroup our Trade Regulation and Antitrust Departments in one section under my leadership with Julián being my deputy.

His new e-mail address is jp@allendebrea.com.ar and his telephone number is 54-11-4318-9907

HOGAN & HARTSON ADDS TO CORPORATE PRACTICE IN NORTHERN VIRGINIA OFFICE

MCLEAN, Va. – Hogan & Hartson L.L.P. announced today that Brian Lynch has joined the firm as a partner in the corporate, securities and finance practice of the Northern Virginia office.

Lynch focuses his practice on capital markets transactions, mergers and acquisitions, venture-capital financings and corporate governance and business transactional matters. He represents boards of directors, investment banks and corporations in a wide range of industries. Lynch has maintained an active practice counseling clients and lecturing on evolving federal securities law developments, including the Sarbanes-Oxley Act.

Before joining Hogan & Hartson, Lynch was a partner with the Northern Virginia office of a national law firm, where he was head of the mid-Atlantic public company practice group from 2000-2004. Prior to this, he was a partner with the Philadelphia office of another national law firm. Before entering private practice in 1990, Lynch was an attorney with the Securities and Exchange Commission, Division of Corporation Finance, where he worked in the Office of the Chief Counsel on rulemaking initiatives.

Lynch holds a law degree from Temple University and a bachelor's degree, *cum laude*, in Accounting and English from LaSalle University.

About Hogan & Hartson
Hogan & Hartson's Northern Virginia office has been providing service to regional, national, and international clients since opening its doors in 1985. The lawyers of the Northern Virginia office are widely recognized for their experience in corporate and securities, technology and intellectual property, mergers and acquisitions, government contracts, labor and employment, real estate and financing transactions, commercial litigation, aircraft finance and estate planning.

Hogan & Hartson is an international law firm headquartered in Washington, D.C., with close to 1,000 attorneys practicing in 20 offices around the globe. The firm's broad-based international practice cuts across virtually all legal disciplines and industries.

For more information about the firm, visit www.hhlaw.com.

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PRAC 35th INTERNATIONAL CONFERENCE
Lima Cusco, Peru
May 15th 21st, 2004

Dear PRAC Members:

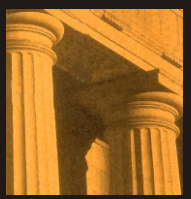
It gives us great pleasure to be the host of the 35th Pacific Rim Advisory Council Conference to be held in Lima and in the historic city of Cusco, Peru, from May 15th to 19th, 2004 and for those attending the follow on programme in Machu Picchu, from May 20th to 21st.

Cusco, a fascinating city steeped in history, tradition and legend, is now the oldest inhabited city in the American continent. The heart of the once mighty Inca Empire, it is the archaeological capital of the Americas, and reveals the various stages and cultures of its Pre-Inca, Colonial and Republican history. The conference program also includes activities in Machu Picchu, the Lost City of the Incas, declared a Cultural and Natural World Heritage Site by UNESCO. The beautifully preserved ruins consist of an enormous stone city hidden by a spectacular terraced green mountain plateau surrounded by three towering peaks. Social events included in the program will present to you Andean typical dances, songs and meals from the different regions of Peru.

As we prepare for your arrival in Peru next month, please let us know if there is anything that we can do for you to enhance your stay. Delegates are reminded to ensure that all travel plans are iconfirmed and in order, including travel documents as necessary.

We look forward to welcoming you in our country, sharing with you our cultural and geographical variety, and extending to you our traditional Peruvian hospitality.

Jorge Pérez-Taiman
Host Committee Chair



MUÑIZ,
FORSYTH,
RAMIREZ,
PEREZ-TAIMAN &
LUNA-VICTORIA
ATTORNEYS - AT - LAW

Advance Confrence Materials are available at www.prac.org Private Libraries

BRIGARD & URRUTIA ADVISE in CAC BOND ISSUE

The Republic of Colombia has completed its first bond issuance of 2004, placing US$500 million of 8.125 per cent global bonds due 2024. This was the first 20-year issuance made by the country.

Citigroup Global Markets Inc and Merrill Lynch Inc acted as underwriters for the issuance. They were advised in Colombia by Brigard & Urrutia, through partner Carlos Urrutia-Valenzuela and associate Carolina Arciniegas.

CLAYTON UTZ RANSK TOP 2003 M&A DEALS

Clayton Utz Mergers & Acquisitions team went from strength to strength in 2003.

A consistent flow of leading roles across our national offices coupled with our involvement on 4 of the year's top 10 deals and almost half of the year's top 15 deals saw us ranked strongly on the Thomson Financial Mergers and Acquisitions Legal Advisor League Tables.

The firm ranked second in number, and third in value, of announced and completed M&A deals with any Australian or New Zealand involvement. Even more impressive, the firm ranked first in value of announced deals involving an Australian or New Zealand target and announced deals involving an Asia-Pacific target.

We are delighted with our success and proud to have the strength of our national team endorsed by so many of Australia's most respected companies and financial institutions.

We thank you for supporting Clayton Utz in 2003 and we look forward to helping you achieve your goals in the coming years.

M&A highlights of 2003

- Advising Constellation Brands on its A$2.472 billion acquisition of BRL Hardy to create the world’s largest wine business by volume
- Acting for UNiTAB on its proposed A$2.4 billion takeover of TAB Limited
- Acting for Boral in its A$840 million off-market takeover offer for Adelaide Brighton
- Acting for BankWest on the A$1.05 billion takeover by HBOS plc.
- Acting for Brickworks on its successful takeover of Bristile (estimated at A$458 million)
- Acting for Mayne Group on the A$813 million sale of its Australian and Indonesian private hospitals
- Advising Queensland Cement on its merger with Australian Cement Holdings to create Australia's largest cement producer

Advising Morgan Stanley and Citigroup as underwriters of ANZ's A$3.6 billion rights issue in conjunction with its acquisition of National Bank of New Zealand.

For additional information about Clayton Utz visit our web site at www.claytonutzlcom

HALE AND DORR CLIENTS NOMINATED FOR THE ANNUAL BREAKTHROUGH ALLIANCE AWARD FOR SIXTH YEAR

For the sixth year in the eight year history of the award, Hale and Dorr LLP has been counsel to at least one nominee for the Breakthrough Alliance Award sponsored by Recombinant Capital—an award given for the best and most innovative practices in drafting and negotiating alliances between biotechnology and pharmaceutical companies. In three of the past seven years in which the award was given, clients of Hale and Dorr took the award home. This year, three of the five nominees are Hale and Dorr clients.

Recombinant Capital annually nominates biotech-pharma alliances as the breakthrough deals of the previous year. The award is bestowed upon the alliance that receives the most votes by biotech and pharma business development and licensing executives.

Hale and Dorr has served as counsel to three of the five Alliance Award nominees this year: Idenix in the agreement with Novartis, focused on viral drugs and worth up to $862 million; Millennium Pharmaceuticals in the potential $500 million marketing deal for Velcade (bortezomib), a proteasome inhibitor for multiple myeloma with Ortho Biotech Products LP, a Johnson & Johnson company; and Eyetech Pharmaceuticals in a potential $750 million deal with Pfizer Inc., centered on developing and commercializing Macugen, Eyetech's lead candidate for age-related macular degeneration and diabetic macular edema.

"We are delighted our clients continue to receive this distinct recognition by their peers in the biotechnology and pharmaceutical industry. Competition has remained fierce over the past seven years—and we expect that competition among the 2004 nominees will be no exception." said Steven Singer, co-chair of the Life Sciences Group at Hale and Dorr.

NAUTADUTILH SECURITIZATION DEALS CONTINUE

The Dutch securitisation market continued to be driven by securitisations of residential mortgages (RMBS), such as (i) SNS Bank N.V. the originator of Holland Mortgage Backed Series (Hermes) VI and VII B.V., (ii) ASR Bank N.V. the originator of Delphinus 2003-I and 2003-II B.V., (iii) GMAC RFC Nederland B.V. the originator of E-MAC NL 2003-I and 2003-II B.V. and (iv) ABN AMRO Bank N.V. the originator of Stichting European Mortgage Securities V.

In addition to the many RMBS transactions, the NautaDutilh Securitisation Team also worked on the first synthetic securitisation in the Netherlands using the Provide programme of Kreditanstalt für Wiederaufbau (Provide Orange 2003-I B.V.) and originated by NIB Capital Bank N.V. Together with the Brussels office, the Securitisation Team worked on the innovative Stellae transaction, whereby lease receivables relating to offices of the EU were sold and assigned to Stellae-I B.V.

For additional information please visit our web site at www.nautadutilh.com

TOZZONI FREIRE TEIXEIRA E SILVA ADVISES AHOLD IN SALE OF BRAZILIAN CREDIT CARD BUSINESS TO UNIBANCO

Brazilian bank Unibanco - União de Bancos Brasileiros SA has acquired credit card company HiperCard from Dutch group Koninklijke Ahold NV, for R$630 million (US$216 million). The deal closed on March 1.

At the same time as this transaction, Ahold sold Bompreço to Wal-Mart. Wal-Mart and Unibanco have already negotiated terms for a new service agreement governing the relationship between HiperCard and Bompreço, which preserves the former business model. The agreement was signed concurrently with the closing of the acquisition.

Tozzini Freire Teixeira e Silva Advogados gave Brazilian counsel to Ahold, through partners André Leal Faoro and Fulvio Pistoresi, and associates Rodrigo Moreira Pinto Beraldo and Marcio de Souza Delgado.

AUSTRALIA – Clayton Utz – Free Trade Agreement - Report

What will the Australia-US Free Trade Agreement mean for Australia? Clayton Utz has prepared an initial analytical overview of the FTA, after carefully reviewing the actual text of the FTA. We've identified some of the major changes which might flow from the FTA, and how that affects Australian business.

It's important to remember that comprehensive treaty arrangements are very complex to negotiate, implement and interpret. A full understanding of such treaties, their effects and the full extent of the opportunities and challenges they create take some time to become fully apparent. We'll provide further information and analysis as the situation develops.

To view or download the report in its entirety, visit our web site at www.claytonutz.com or you may link directly here: http://www.claytonutz.com./downloads/CUFTA_Report2.pdf

NEW ZEALAND Simpson Grierson – Recent Media Related Rulings

The Court of Appeal and a full bench of the High Court have recently given two very important decisions in media related cases. The first is Hosking v Runting & Ors which deals with privacy. It can be found at the following site: http://www.courts.govt.nz/judgment/

The High Court decision in *The Solicitor-General for New Zealand v Smith & Ors* can also be found on this site.

In the *Hosking* decision, the Court of Appeal found by a majority that there is a tort of interference or invasion of privacy in New Zealand.

In what I consider to be the leading judgment, Gault P and Blanchard J say that there are two fundamental requirements for a successful claim for interference with privacy:

> The existence of facts in respect of which there is a reasonable expectation of privacy; and
>
> Publicity given to those private facts that would be considered highly offensive to an objective reasonable person.

These two Judges say that no Court can prescribe all the boundaries of a cause of action in a single decision and that the claim will evolve through future decisions as Courts assess the nature and impact of particular circumstances. They emphasis however that they are concerned only with wrongful publicity given to private lives. They are not concerned at this time with unreasonable intrusion into a person's solitude or seclusion. In many instances this aspect of privacy will be protected by the torts of nuisance or trespass or by laws against harassment, but this may not always be the case.

These two Judges say that private facts are those that may be known to some people, but not to the world at large. There is no simple test for what constitutes a private fact. They further say that the right to privacy is not automatically lost when a person is a public figure, but his or her reasonable expectation of privacy in relation to many areas of life will be correspondingly reduced as public status increases. Involuntary public figures may also experience a lessening of expectations of privacy, but not ordinarily to the extent of those who willingly put themselves in the spotlight. They say the special position of children must not be lost sight of.

The concern of the law so far as these Judges are concerned is with widespread publicity of very personal and private matters. Similarly publicity, even extensive publicity of matters which, although private, are not really sensitive should not give rise to legal liability. ***The concern is with publicity that is truly humiliating and distressful or otherwise harmful to the individual concerned.***

Most important there should be available in cases of interference with privacy a defence enabling publication to be justified by a legitimate public concern in the information.

Tipping J held that a tort of invasion of privacy exists. To him the first and fundamental ingredient of the tort should be that the plaintiff must be able to show a reasonable expectation of privacy in respect of the information or material which the defendant has published or wishes to publish. The necessary expectation can arise from the nature of the information or material or the circumstances in which the defendant came into possession of it or both. In most cases that expectation is unlikely to arise

unless publication would cause a high or substantial level of offence. It should be a defence to an action for invasion of privacy that the information or material published about the plaintiff's private life is a matter of legitimate public concern.

Keith J and Anderson J in separate judgments consider that there should be no tort of invasion of privacy. Keith J based his conclusion on the central role of the right to freedom of expression; the existing protections of privacy interests under the Privacy Act, Broadcasting Act, Press Council Rules and the like; and the lack of an established need for the proposed cause of action. He found it significant that a general provision on privacy was deliberately excluded from the Bill of Rights. Anderson J emphasised the concern that the right to freedom of expression, affirmed by s14 of the New Zealand Bill of Rights Act 1990, is now to be limited because publication of truth, might be *"highly offensive to an objective reasonable person"*. Anderson J considered that cases such as *Douglas and Zeta Jones* could have been dealt with on conventional bases of contract and trespass. The photographs could only have been taken by a person who was either not invited and therefore a trespasser, or by an invitee who breached a significant stipulation of the license to be present.

In *The Solicitor-General for New Zealand v Smith & Ors* the High Court found the outspoken opposition MP (and former high-ranking cabinet minister) Nick Smith, TV3 and Radio New Zealand guilty of contempt. Dealing with each in turn.

Nick Smith

Smith was found in contempt by putting improper pressure on litigants by a telephone call that he made to a caregiver who had interim custody of a child. The Court said Smith had an *"actual intention of persuading the caregiver to give up the case and surrender custody of the child"*. The Court said his public statements on Radio New Zealand, and his media release were *"one-sided, emotive and extreme in terms of their language, and inflammatory and intimidatory (particularly of the caregiver) in their effect"*. Even though Smith did not mention the names of the parties there was a breach of s27A of the Guardianship Act. His statements amounted to a contempt as well.

The Court also found that Smith intended to influence the Family Court decision and intended to lessen public acceptance of its decision on the case. Smith undermined public confidence in the Court by the language he used. It amounted to an assault on the authority and integrity of the Court and the fairness and legitimacy of its decision.

It is important to stress that the focus was on the *probable tendency* of the publication, rather than its actual effect. Referring to previous authority the Court said:

> "*It encompasses the unfair and intemperate comment of someone who has set out to inhibit a litigant, regardless of whether the comment actually succeeds in doing so. A weak litigant needs protection against unfair publicity deliberately intended to undermine its position.*"

Most important the Court adopted an interpretation of *"report of proceedings"* contrary to TVNZ's (and other media) interest. It said that the phrase covered the reporting of the *initiation of a case and of all stages of it*. It could even include the fact of saying that Family Court proceedings had been commenced.

As I have previously advised, there is conflicting authority in the High Court. In particular Holland J in *TVNZ v Department of Social Welfare* (1990) confined the term to a report of *what actually took place in the Courtroom*. This is the interpretation we have relied on in the past.

We now have competing High Court authority. The conflict will have to be cleared up by the Court of Appeal.

As to whether or not conduct may interfere with the Court, the Judges said these are the factors that need to be considered:

- Whether the issues for the Judge are factual or purely legal.
- Any element of discretion involved in the Judge's decision.
- The tone of the publication.
- The focus of the publication: was it directed at achieving a particular result?
- Whether the publicity includes information/observation that would be inadmissible in Court.

TV3

The "*20/20*" documentary *"Tug of Law"* was found to be in contempt by the intention (and effect) of putting pressure on the caregiver to forego her claim to custody. The Court emphasised its impressions of the programme:

The implicit if not explicit bias in the commentary. It was present right from the outset when the presenter stated:

> "*If you are one of the country's two million parents you might find the following programme disturbing. It is about parents' rights or lack of rights to have custody of their own children …*"

And it continued right through to the end:

> "*Time's up. It's the day they know their son has to go, a very special family day captured on home video. It's the day of his father's birthday and the day the world celebrates Mothers Day, the very day the system chose to take the family's youngest brother and son away …*"

The selection of images and scenes. One example was the picture of the whole family with the child's face pixillated, and then the removal digitally of the child leaving a gap in the family group. Another was the shots of the mother coming out of the Court after the hearing of the caregiver's application for a warrant to return the child to her, and tearfully announcing the outcome on the telephone to the father.

The depiction of the child relaxing and playing happily with the family both inside and outside their home in Nelson, **contrasted** with the somewhat barren scenes of the caregiver in the porch of her house in Wellington, and a child entertaining itself bouncing a ball down a street. The comparison was seen as deliberately odious.

The depiction of the family as healthy, hard working and closely knit, versus depiction of the caregiver as a poor parent with quite explicit suggestions that she has seriously neglected the child's education, development and health and exposed him to violence through living with a partner who has criminal convictions for violence. There was an image of an unidentified document in which the caregiver conveyed a threat to shoot the parents if they attempted to take the child.

Representing the arrangement under which the child went to live with the caregiver as a temporary one, when that was fundamentally disputed by the caregiver.

The Court specifically rejected TV3's attempt to excuse the one-sidedness of the programme by relying on the caregiver's refusal to participate in it. Quite apart from her obligations under s27A of the Guardianship Act, the Court said that the caregiver must not be placed in the position of having to make her case on television rather than in Court in an effort to prevent public obloquy.

The Court referred to the fact that television is widely acknowledged to have a more powerful reach than radio, or the print media. That follows from its ability to depict people and places in a way that can manipulate the emotions of viewers.

Accordingly the Court found that TV3 also intended to influence the decision of the Court, or at least create a risk of such influence. Although the programme may not have intended to undermine public confidence in the Court, it carried **a real risk of this**. The public interest defence did not apply. Nor was it a defence that Judge Mahoney had opened the gate by commenting himself. The Chief Family Court Judge was found to be in *"damage control"* and trying not to be drawn into comments on the particular case.

The Court said that the "Tug of Law" item was a report of proceedings.

> "*We regard the "Tug of Law' documentary as a report of the proceeding. It describes the nature of the dispute, reports on the Court's decision and identifies the parties by their first names. It also identifies the locality of the parties. Even accepting (which we do not) that the previous publications by Dr Smith and/or RNZ somehow justified TV3 in publishing the same thing, the "Tug of Law" documentary put in the public arena significant detail that was not already there. For example, it described the primary proceeding and also the nature and outcome of the warrant application, gave the first names of the child's parents and siblings, stated that the family lived in Nelson and had enrolled the child at Stoke Primary School, and sought to convey the emotions and relationships within the family. The caregiver's evidence was that children at the child's school had teased the child following the programme. It is clear that those children (or their parents) had been able to identify the parties involved.*"

Radio New Zealand

Finally Radio New Zealand was found to have put improper pressure on the caregiver by broadcasting the interview with Smith. The Judges were critical of Linda Clarke's programme for talking about details of the case, and for the inadvertent release of the name of the child. It also said that there was a real tendency to influence the Family Court in its decision.

Conclusion

In conclusion, the decision is a restrictive one as far as the media are concerned. Contempt by scandalising the Court is alive and well. Also contempt by attempting to dissuade a litigant, and litigants generally from having disputes decided by the Court.

It can be argued however that Nick Smith's language was extreme and that this is an exceptional case. Smith referred to: "*This case almost amounts to state sanctioned child stealing*". He described the Court's interim decision as *"blatantly wrong"* and *"a travesty of justice"*. He described what had happened as *"obscene"*, *"a fiasco"*, and *"an indefensible situation"*. He also referred to *"a warrant (from the Court) for the child to be ripped out of his family's arms"*. The Court also accepted that he referred to *"Parliament is the highest Court in the land"* in his telephone discussion with the caregiver.

These extreme comments, combined with the one-sided "*20/20*" programme, and RNZ's delving into the facts of the particular case have resulted in the contempt charges being commenced by the Solicitor-General and upheld by the Court.

On Friday 2 April, the Judges fined Nick Smith $5,000. They said he intended to get one of the litigants in the case to abandon her claims on the child concerned, and undermined the legitimacy of the Family Court. The Judges however praised his generosity to the family concerned and said his aim was worthy. They noted the huge cost Nick Smith had already incurred and said the conviction for contempt was punishment enough, and imposed a relatively small penalty. The Judges fined TV3 $25,000. They described its documentary about the Family Court as opportunistic, cynical and wrong. Radio New Zealand was fined $5,000. Its offence was in broadcasting the live interview with Nick Smith.

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William is a senior litigation and dispute resolution partner, with broad experience in all aspects of commercial, civil and property litigation and fraudulent transactions. Based in Simpson Grierson's Auckland office, he is one of New Zealand's foremost defamation and media lawyers.

William has appeared in numerous high profile High Court and Court of Appeal media law cases, covering defamation, privacy, contempt, suppression orders, New Zealand Bill of Rights, Broadcasting Standards and one of the leading cases in New Zealand on censorship. He has acted as general counsel to Television New Zealand Ltd for many years. He regularly provides pre-publication counselling. For additional information on this or other related matters please contact William Akel directly or visit our web site at www.simpsongrierson.com

FOCUS

MOF OFFERS ADVANCED TAX RULINGS

Kuei-Fang Yung

On 31 December 2003, the Ministry of Finance (MOF) issued the Regulations Governing Advanced Tax Ruling, which took effect on 1 January 2004. From 1 January 2004, taxpayers intending to conduct transactions meeting the requirements set forth in the regulations may apply to the MOF for an advanced tax ruling on issues concerning tax implications of such transactions. The MOF hopes that this service will help to establish consistency and certainty in the application of tax laws, and reduce disputes between taxpayers and the tax collection authorities, thus encouraging taxpayers to make full and truthful tax filings, and will also enable parties to transactions to conduct tax planning to reduce risks. The main points are outlined below:

I. Eligibility

An advanced tax ruling is available for an international tax case involving a cross-border transaction or investment that an applicant intends to make within one year, and that meets either of the following conditions:

- The value of the investment, not including that in land, is at least NT$200 million, or the value of the first transaction is at least NT$50 million.
- The investment or transaction will create significant benefits to the economy of the ROC.

II. Grounds for Refusal

If an application does not meet the above criteria, or in any of the following circumstances, the MOF will not render an advanced tax ruling:

- Determination of mere facts or the value of assets.
- Hypothetical transactions, or transactions that will not be executed within one year.
- Transactions that have already taken place, or where related tax filings are about to be made or have already been made.
- The main issues in the case are similar to those in a case that is currently the subject of an administrative remedy procedure.
- The information supplied by the applicant is incomplete, and the applicant fails to supply additional information within a specified period upon notice.
- Statements of material information are incorrect or misrepresented.
- The content of the application mainly concerns the determination of the basis for computation of income, costs, or expenses as referred to in Article 43-1 of the Income Tax Act.
- The application requires the interpretation of law other than tax law.
- The application requires the interpretation of foreign laws.
- The purpose of the application is tax evasion, and not a transaction that the applicant is seriously considering undertaking.

- Other cases in which it would be inappropriate to render an advanced tax ruling.

III. Case Handling

- The MOF will establish an Advanced Tax Ruling Committee to examine cases and issue rulings. The service will be entirely free of charge.

- The MOF should inform an applicant within one month from the second day of receipt of an application or supplementary documents whether it will provide an advanced tax ruling, and should complete its ruling within three months from the same date. If it is unable to complete the ruling within that time, it may make a single extension before the prescribed handling period has expired.

- An applicant may withdraw his application at any time before a ruling is delivered. But after withdrawing an application, he may not make another application based on the same facts.

IV. Legal Force of Rulings

A ruling made under the advanced tax ruling procedure has the same legal force as an interpretation ruling issued by the MOF.

Davis Wright Tremaine LLP

Health Law Advisory Bulletin

CMS Issues Average Sales Price Reporting Regulations

By Kathleen H. Drummy
[April 2004]

On April 6, 2004, Centers for Medicare & Medicaid Services (CMS) issued an interim final rule to implement provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) regarding the calculation and reporting of the Average Sales Price (ASP). MMA significantly reformed payment for outpatient drugs and biologicals ("drugs"), such that beginning in 2005, Medicare payment for most outpatient drugs will be determined with at least some reference to the ASP. Under MMA, physicians and suppliers will elect to either buy and bill the drugs directly, with payment for the drug under an ASP methodology, or to obtain drugs from a retail pharmacy or distributor selected under a competitive acquisition program, in which case the pharmacy or distributor would bill Medicare for the drug.

These interim final ASP regulations primarily deal with the methodology to be used by manufacturers in reporting quarterly ASP data to CMS, beginning with the first calendar quarter of 2004. The regulations are issued on an emergency review basis because this ASP data must be submitted for the first calendar quarter by the statutory deadline of April 30, 2004. However, CMS will accept and consider comments on the rule for the 60 days following issuance. Such comments may impact on the reporting and other policies applicable to later quarters. In light of the downstream importance of ASP, however, distributors and providers also have an interest in ASP reporting and reimbursement provisions.

CMS plans to issue a later rulemaking regarding other aspects of the ASP payment system. CMS has informed Davis Wright Tremaine LLP that additional guidance will be published in a Question and Answer format at www.cms.gov, possibly by April 9, 2004.

The Regulations

The regulations are brief and refer to the Medicaid Best Price Statute. Unfortunately, the Medicaid Best Price Statute is broad and its terms are defined primarily in rebate agreements, rather than in regulations. Even when considered together, the Medicaid Best Price Statute and the regulations may not provide sufficient guidance to manufacturers in reporting ASP data, particularly by the April 30, 2004 deadline.

MMA and the regulations define "manufacturer" broadly to cover entities that are engaged in the production or similar preparation and sale of the drugs or in the packaging or similar distribution of the drugs. Wholesale distributor of drugs or retail pharmacies licensed under state law are not considered manufacturers.

The regulations do not identify by name or National Drug Code (NDC) which drugs are covered by the reporting requirements. Each of the affected drugs, however, should have been assigned one or more NDCs. While most outpatient drugs covered by Medicare Part B are subject to the ASP reporting requirements, certain drugs, such as radiopharmaceuticals, will not be paid under these methods and will not be subject to ASP reporting requirements. Manufacturers will need to identify the drugs which must be reported under these regulations.

On a quarterly basis, each manufacturer must calculate its ASP and submit the data to CMS within 30 days of the close of that quarter. The ASP for each manufacturer is calculated for each calendar quarter using the 11-digit NDC for the manufacturer's sales to all purchasers in the United States. Sales that are exempt from the Medicaid Best Price calculation and sales which are nominal in amount are excluded. The remaining sales are divided by the total number of units of that NDC sold by the manufacturer in that quarter.

In calculating the ASP, the manufacturer must deduct various discounts, including prompt payment discounts which previously had not been required to be offset under the Medicaid Best Price Statute. The MMA also requires that where there is a lag in the reporting of chargeback and rebate information, such so that adequate data is not available for the quarterly report, an estimate based on a 12-month rolling average will be used. The regulations in addition require this estimation method be used for discounts.

The regulations further define nominal sales by reference to the Medicaid Best Price Statute, but that term is not defined in that statute. Although regulations proposed in 1995 regarding the Medicaid Best Price Statute defined "nominal" to mean less than 10 percent of the average manufacturer price (AWP), those proposed regulations were never finalized. The Medicaid National Rebate Agreement also includes this definition, but as AWP differs in a variety of ways from ASP, further guidance may be required to identify the type of nominal sales which may be excluded from the ASP calculation.

Management at pharmaceutical companies will be eager to have these ambiguities resolved. Each quarterly report must be certified by the manufacturer's Chief Executive Officer, Chief Financial Officer or an authorized individual who reports directly to the CEO or CFO. The ASP data must be submitted in Microsoft Excel, using the template provided by CMS, who also provides a sample form for identifying the manufacturer's contact for purposes of the ASP report and for certifying the ASP report. Although the CMS certification form is not expressly required to be used, some form of certification of the data will be required. The language of the sample certification is similar to that used in Medicare cost reports, to the effect that the submission is accurate to the best of the signer's knowledge and made in good faith.

Because the regulations specify civil monetary penalties for misrepresentations, submission of false information and failure to submit timely information, the certification as to the form and accuracy of the report merits care and attention. Certifications later alleged to be incorrect have been made the basis of enforcement actions under the False Claims Act. In that regard, the MMA amendments make clear that the reported information will be subject to audit by the Office of Inspector General.

The regulations specify that each price misrepresentation carries a penalty of up to $10,000 for each day in which the price misrepresentation was applied. However, reference to the Medicaid Best Price Statute is necessary to understand that the penalty for failure to provide timely information is increased $10,000 for each day of delinquency and that the penalty for each item of false information may be as much as $100,000.

Judicial review of many determinations regarding ASP will not be available. Because ASP will affect payments beginning in 2005, clear and understandable ASP rules are important not only to manufacturers, but also distributors and providers. Interested parties should consider commenting on the regulations, even if the impact is more immediately on manufacturers. Manufacturers might review their internal processes to determine what changes might be helpful in the accurate compilation of data and verification of the ASP quarterly reports. Pharmaceutical manufacturers might also be mindful of the issues raised in the OIG guidelines in establishing procedures to demonstrate good faith efforts to comply with the hastily issued interim final regulations.

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