Background

The Ministry of Health and Long-Term Care receives a significant number of inquiries about hospital charges to out-patients for provision of drugs. The ministry investigates each inquiry under authority of, and by the process set out in, the *Commitment to the Future of Medicare Act* (CFMA) which prohibits charges for insured services (extra-billing).

This INFOBulletin reminds hospitals of the provisions in Regulation 552 under the *Health Insurance Act* (HIA) that apply to the provision of drugs to out-patients.

Legal Framework

Insured hospital services are set out in sections 7 and 8 Regulation 552 under the *Health Insurance Act* (HIA). In accordance with section 8(1) of Regulation 552, the supply of drugs, biologicals and related preparations that are prescribed in accordance with accepted practice by a physician on the medical staff, a midwife on the midwifery staff, an oral and maxillofacial surgeon on the dental staff or a registered nurse on the extended class nursing staff of the hospital, and that are administered in the hospital, are services that a registered out-patient of the hospital is entitled to receive without additional charge. Dedicated or special funding for a service does not impact the determination of whether or not a service is insured.

The provision of drugs, biologicals and related preparations are not insured hospital services in circumstances set out in section 8(1)5 of Regulation 552. These are:

i. the provision of any proprietary medicine as defined from time to time by the regulations made under the Food and Drugs Act (Canada);

ii. the provisions of medications for the patient to take home with exceptions as set out in section 8(2) of Regulation 552;
iii. diagnostic services performed to satisfy the requirements of third parties such as employers and insurance companies; and
iv. visits solely for the administration of drugs, vaccines, sera or biological products.

Exclusions to insured hospital services are set out in section 24(2) of Regulation 552.

Policy: Administration of drug is “sole reason” for hospital out-patient visit

Hospital out-patient visits that are solely for the administration of drugs, vaccines, sera or biological products are not hospital services that a registered out-patient is entitled to receive without charge as set out in section 8(1)5 iv of Regulation 552. This provision does not exclude the administration of drugs, vaccines, sera or biological products from insured hospital services when:

- The product cannot be safely stored, prepared and/or disposed in a non-hospital setting or for example, radio-active products.
- The product cannot be safely administered in a non-hospital situation, for example, due to individual patient condition or requirements for inter and post-administration assessment, evaluation and/or interventions that are generally not available in a non-hospital type setting.
- The incidence, severity or unpredictable adverse or untoward effects of the product require that emergency life-saving equipment and/or specialized medical and nursing staff be immediately available to intervene. This would be indicated, for example, in hospital policy or care plans, a drug monograph and medical research.
- Administration of the product requires an associated service or it is required in support of an associated service that is not generally available in a non-hospital type setting. Examples include, but are not limited to:
  - It is medically necessary to administer the drug under anaesthesia.
  - Administration of the drug is a necessary adjunct to an insured diagnostic or treatment service.
  - Radiology, ultrasound, EMG or other specialized technology is required to locate drug injection site(s).
  - It is provided as an adjunct to an insured surgical procedure.
- Individual patient circumstances require that the product be administered in a hospital setting. Each case is evaluated on the individual patient condition, need and risk, and environmental factors at the time of the service.

An out-patient visit may include one or more services that are wholly unrelated to the administration of a drug, vaccine, sera or biological product. In this situation the unrelated service is not a determinant of whether or not administration of the drug, etc., is insured.

Advisement

The ministry recommends that hospitals be familiar with the:
- HIA and Regulation 552 provisions that speak to insured hospital services; and
- Part II of the CFMA which prohibits unauthorized payments for insured services (extra-billing) and preferred access (queue-jumping).
This INFOBulletin is a general summary provided for information purposes only. In the event of a discrepancy between this INFOBulletin and the HIA, CFMA, IHFA and Regulations, the text of the law prevails. For complete text, health care providers are directed to review the HIA, Regulation 552 under the Act, the Schedules under Regulation 552, the CFMA and the IHFA. Ontario laws and regulations are available on-line at www.e-laws.gov.on.ca.