

Guidelines regarding re-use of medical devices

994. DR. VIKAS MAHATME: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Government has issued any guidelines with regard to prohibiting the re-use of disposable medical items, like the same gloves being used for several patients, if so, the details thereof, including the list;
- (b) the number of cases registered against hospitals in last three years for such use and whether the affected patients have been reimbursed for the same;
- (c) whether there is any regulation on re-sterilization of such devices and of obtaining special consent from patients to permit use of such re-sterilized items; and
- (d) the steps taken to ensure that cost saved by re-sterilization is passed on to the patients?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) to (d) The Government of India has enacted the Clinical Establishments (Registration and Regulation) Act., 2010 and notified Clinical Establishments (Central Government) Rules, 2012 for registration of Clinical Establishments with a view to prescribe the Minimum Standards of facilities and sendees provided by them. Under the said Act, the National Council for clinical establishments has approved Minimum Standards for different levels of hospitals. These minimum standards *interalia* provide that the hospitals should have adequate drugs, medical devices and consumables commensurate to the scope of services and number of beds. These standards further provide that the quality of drugs, medical devices and consumables shall be ensured. The Hospitals are also required to follow standard precautions like practicing hand hygiene, use of personal infection equipment etc. and infection control practices including compliance to Bio-Medical Waste Management Rules to reduce high risk of healthcare associated infection. Currently, the Act has been adopted by 11 States namely, Sikkim, Mizoram, Arunachal Pradesh, Himachal Pradesh, U. P., Bihar, Jharkhand, Rajasthan, Uttarakhand, Assam and Haryana and all Union Territories except Delhi. The implementation and enforcement of the said Act falls within the ambit of the States/Union territories.

As per Constitutional provisions, 'Health' is a State subject and such issues would generally be addressed to the State/Union Territory concerned for taking

appropriate action as per the provisions of Act and Rules applicable in the concerned State/UT. Data regarding the complaints received by States and action taken by the State to reimburse the affected patients is not maintained Centrally.

Further, Central Government has published Medical Devices Rules, 2017 effective from 01.01.2018. As per the said rules, Medical Device intended to be used for single use should be labeled appropriately.

Monitoring of healthcare service provided under PPP mode

995. DR. R. LAKSHMANAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether it is a fact that healthcare services under Public Private Partnership mode are being offered across the country;
- (b) if so, the details thereof;
- (c) whether Government has put in place any comprehensive policy to control/regulate/monitor the private service providers entering into healthcare services;
- (d) if so, details thereof; and
- (e) if not, reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) and (b) Yes. Public Health and Hospitals is State subject. National Health Mission offers flexibility to the States to provide healthcare services under Public Private Partnership mode depending upon its requirements.

Under the National Health Mission (NHM), technical and financial support is provided to States/UTs to strengthen their healthcare systems, based on the requirements posed by the States/UTs in their Programme Implementation Plans (PIPs). This includes support for provision of healthcare services through Public Private Partnership mode for projects/programmes such as Pradhan Mantri National Dialysis Programme, Free Diagnostic Service for high end low volume tests like Teleradiology Services and CT Scan Services, Ambulance Services, Biomedical Equipment Management Maintenance Programme, National Quality Assurance Programme and other ancillary services duly sharing the suggested guidelines with them.