Standards supporting telemedicine

Steven Phua
Enterprise Singapore

Kevin Tan
Singapore Manufacturing Federation –
Standards Development Organisation

Outline

1. Standards supporting healthcare sector

2. Standards for telemedicine

Quality & Standards (Q&S) supports the growth of Singapore's industries and enterprises

Enterprise Singapore

Build Trust in Singapore Products, Services and Enterprises

Quality Products & Services

Excellent Organisations

Market Opportunities

Health, Safety & Environment

STANDARDS/ ACCREDITATION (ESG)

- International and Singapore Standards
- Measurement Standards (under NMC)
- Accreditation Schemes

CONFORMANCE (PRIVATE SECTOR)

- Testing, Inspection and Certification

REGULATIONS (WHOLE OF GOVT)

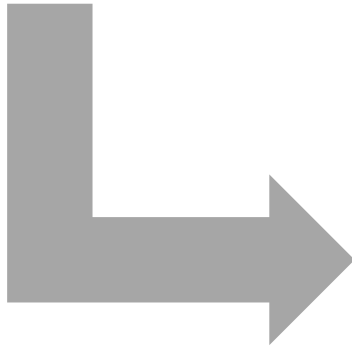- Regulatory requirements (e.g. consumer product safety, building regulations)

Singapore Standards Council

- Enterprise development agency and national standards body for Singapore

- ESG appoints an industry-led Standards Council (SSC) to develop Singapore Standards

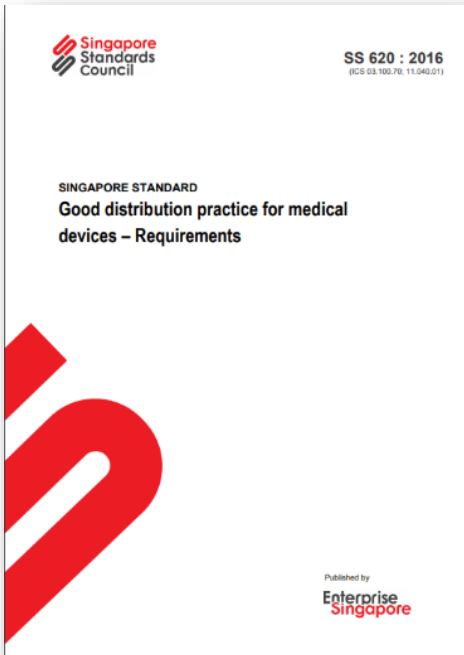- Biomedical and Health Standards Committee (BHSC)*

- Managed by the Singapore Manufacturing Federation – Standards Development Organisation appointed by ESG

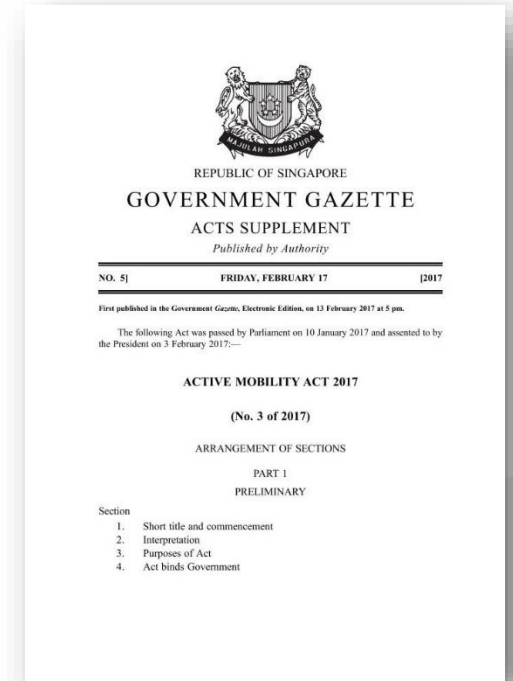Standards Development Organisation

Standards versus regulations

Standards

Singapore Standards Council

SS 620 : 2016
(ICS 03.100.70; 11.040.01)

SINGAPORE STANDARD
Good distribution practice for medical devices – Requirements

Published by
Enterprise Singapore

- Developed by national, regional or international standards bodies
- Non-mandatory*
- Can complement regulations by providing specific guidance to meet regulatory requirements
- Examples:
  - Codes of practice/Guidelines
  - Management systems
  - Specifications
  - Methods of test

Regulations

- Developed by regulators (e.g. MOH, SMC)
- Mandatory (enforced by regulator)
- Examples:
  - Acts (e.g. Medical Registration Act, Private Hospital and Medical Clinics Act Infectious Disease Act
  - SMC Ethical Code

REPUBLIC OF SINGAPORE
GOVERNMENT GAZETTE
ACTS SUPPLEMENT
Published by Authority

NO. 5]   FRIDAY, FEBRUARY 17   [2017

First published in the Government Gazette, Electronic Edition, on 13 February 2017 at 5 pm.

The following Act was passed by Parliament on 10 January 2017 and assented to by the President on 3 February 2017:—

ACTIVE MOBILITY ACT 2017

(No. 3 of 2017)

ARRANGEMENT OF SECTIONS

PART 1
PRELIMINARY

Section
1. Short title and commencement
2. Interpretation
3. Purposes of Act
4. Act binds Government

*All standards are voluntary unless being referenced as part of regulations

Example: Supporting safe point of care testing (POCT) in Singapore

Enterprise Singapore

Safe & Reliable Point of Care Testing in Singapore

STANDARDS/ ACCREDITATION (ESG)

- ESG works with healthcare sector to adopts POCT standards & develops accreditation scheme that support POCT

CONFORMANCE (PRIVATE SECTOR)

- Accredited testing labs/institutions delivers POCT services

REGULATIONS (WHOLE OF GOVT)

- Supports MOH/HSA's regulatory objectives of safe and reliable POCT services

Standards support adoption of new technologies

Standards contain knowledge in a format that is implementable by industry

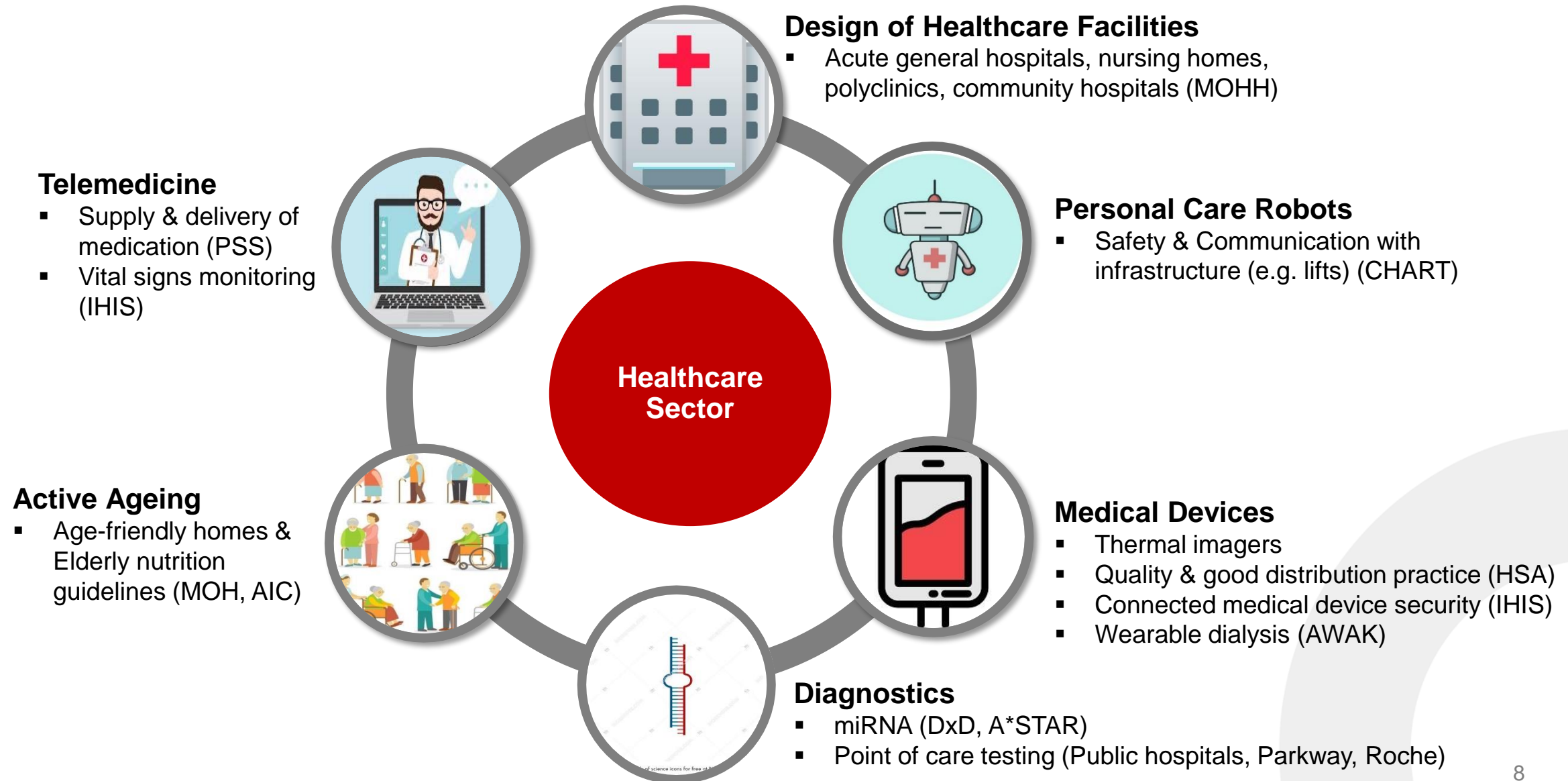Standards facilitate interoperability between new and existing products, services and processes

Standards can ensure products and services address requirements for health, safety and environment

Example: Wearable Dialysis Device

AWAK

- AWAK Technologies developed a patented sorbent technology for wearable dialysis devices to transform patient care.

- **Influenced the drafting of international standards** and ensure that its technologies were incorporated in the requirements of the standards. Helped **assure both regulators and future users of safety and reliability**

7

ESG worked closely with healthcare players to develop standards for new medical technologies, systems and processes

Enterprise Singapore

Healthcare Sector

Design of Healthcare Facilities
- Acute general hospitals, nursing homes, polyclinics, community hospitals (MOHH)

Personal Care Robots
- Safety & Communication with infrastructure (e.g. lifts) (CHART)

Medical Devices
- Thermal imagers
- Quality & good distribution practice (HSA)
- Connected medical device security (IHIS)
- Wearable dialysis (AWAK)

Diagnostics
- miRNA (DxD, A*STAR)
- Point of care testing (Public hospitals, Parkway, Roche)

Active Ageing
- Age-friendly homes & Elderly nutrition guidelines (MOH, AIC)

Telemedicine
- Supply & delivery of medication (PSS)
- Vital signs monitoring (IHIS)

8

Standards supporting enhanced patient care
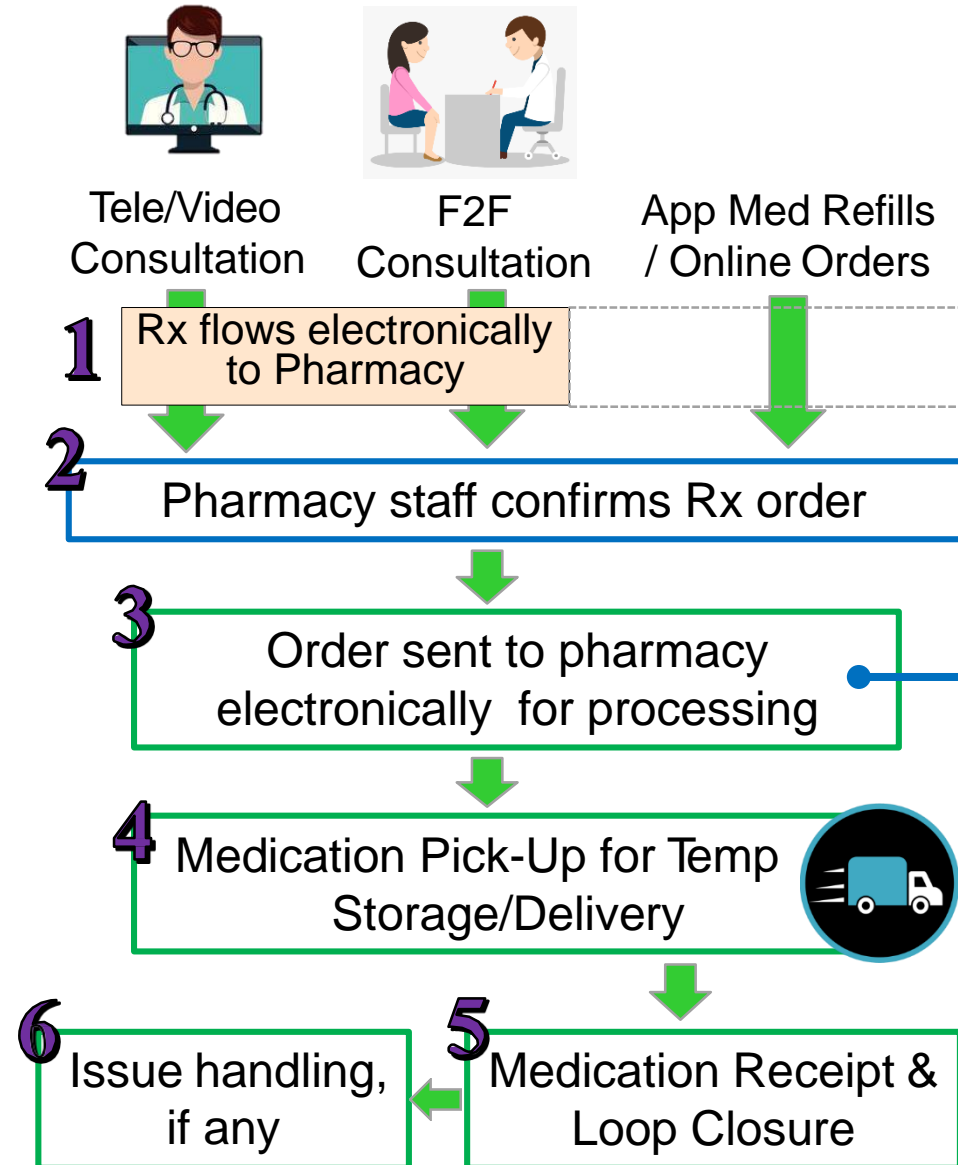## *Use case: Supply & delivery of medication (SS 644)*

The Straits Times – 6 Oct 2019

Patient Abdul Muhammad Danial with his mum Salmi Basar and dad Azman Ab Jalil. The boy's medicine is delivered to his home in Choa Chu Kang. Mr Azman says the service is very helpful as it saves him time travelling to and from the hospital – time that he can spend with his son.

- Helps patients avoid unnecessary trips to pharmacies to collect medicines. Allows patients and care givers to focus on health and care giving responsibilities.

- Ensures that medication is **delivered safely and securely to patients/care givers**.

- **Widely adopted by public hospitals, polyclinics and recommended in MOH/SMA telemedicine guidelines.**

- ESG worked closely with the healthcare sector including the Pharmaceutical Society of Singapore. MOH, public & hospitals/polyclinics and private sector players.

.

Example: Healthcare Model with Central Fill Pharmacy (CFP) support

Examples of Implementation – Packing Standards

Enterprise Singapore

Tele/Video Consultation

F2F Consultation

App Med Refills / Online Orders

1 Rx flows electronically to Pharmacy

2 Pharmacy staff confirms Rx order

3 Order sent to pharmacy electronically for processing

4 Medication Pick-Up for Temp Storage/Delivery

5 Medication Receipt & Loop Closure

6 Issue handling, if any

3 Tamper-evident opaque bag
(Home delivery/Locker boxes)

- Tamper-evident Seal
- Special Handling Instruction
- Label for Delivery Details
- Opaque Bag for Confidentiality & Protection

Delivery carton with serialised cable tie
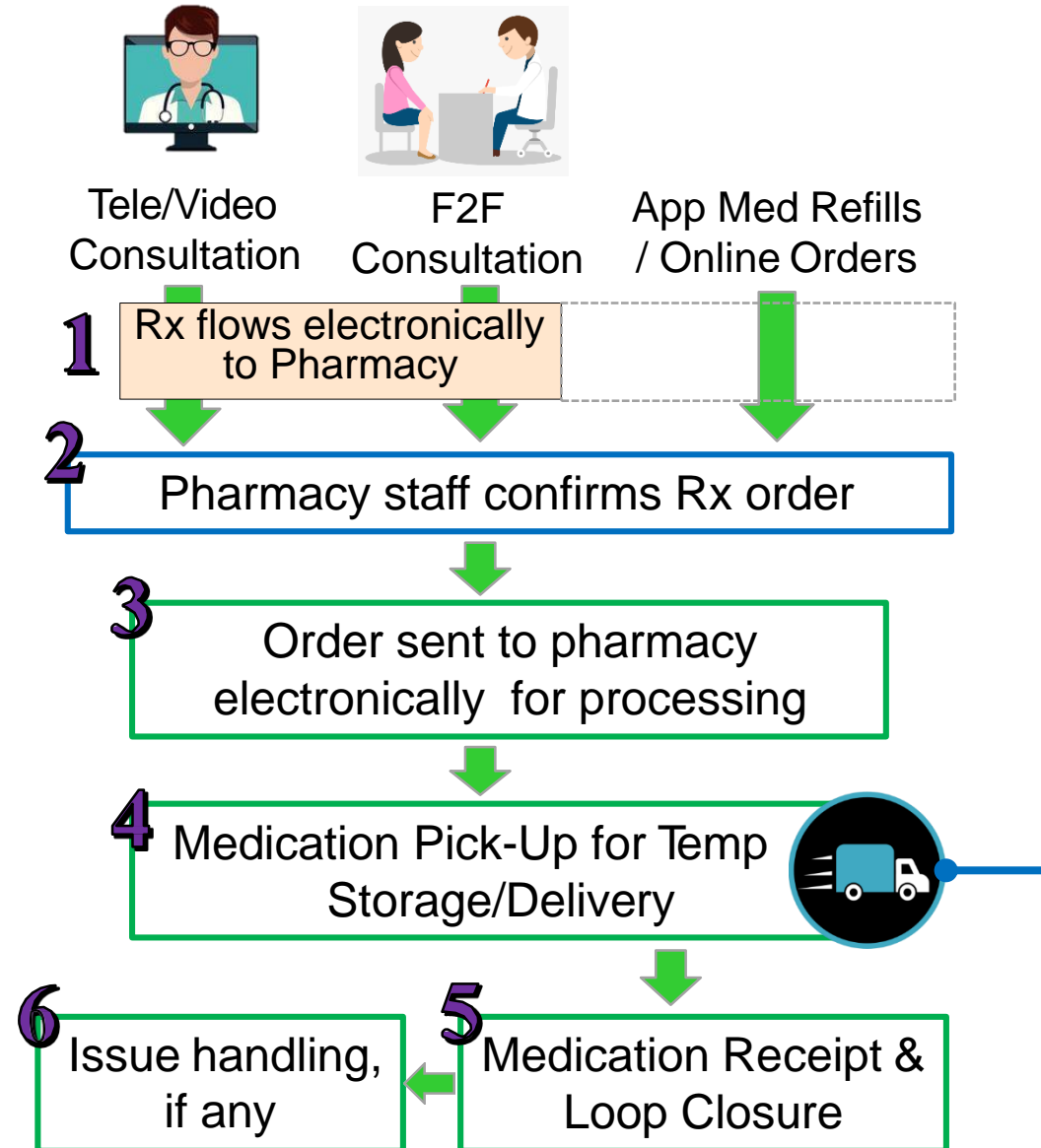(Delivery to institutions/medical clinics)
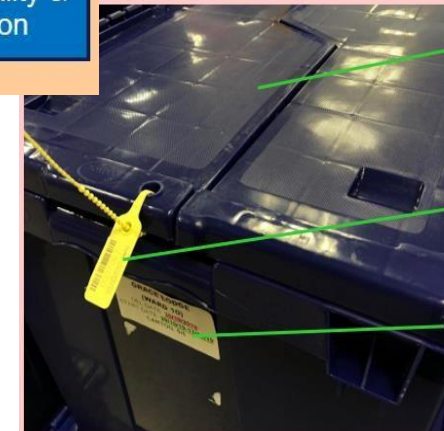
- Opaque Carton for Confidentiality & Protection
- Serialised Cable Tie
- Label for Delivery Details

Similar bag designs used for polyclinic HD

Shared by NHG Pharmacy Dept and Central Fill Site

Example: Healthcare Model with Central Fill Pharmacy (CFP) support

Examples of Implementation – Storage & Delivery Conditions

Enterprise Singapore

Tele/Video Consultation

F2F Consultation

App Med Refills / Online Orders

1 Rx flows electronically to Pharmacy

2 Pharmacy staff confirms Rx order

3 Order sent to pharmacy electronically for processing

4 Medication Pick-Up for Temp Storage/Delivery

5 Medication Receipt & Loop Closure

6 Issue handling, if any

4

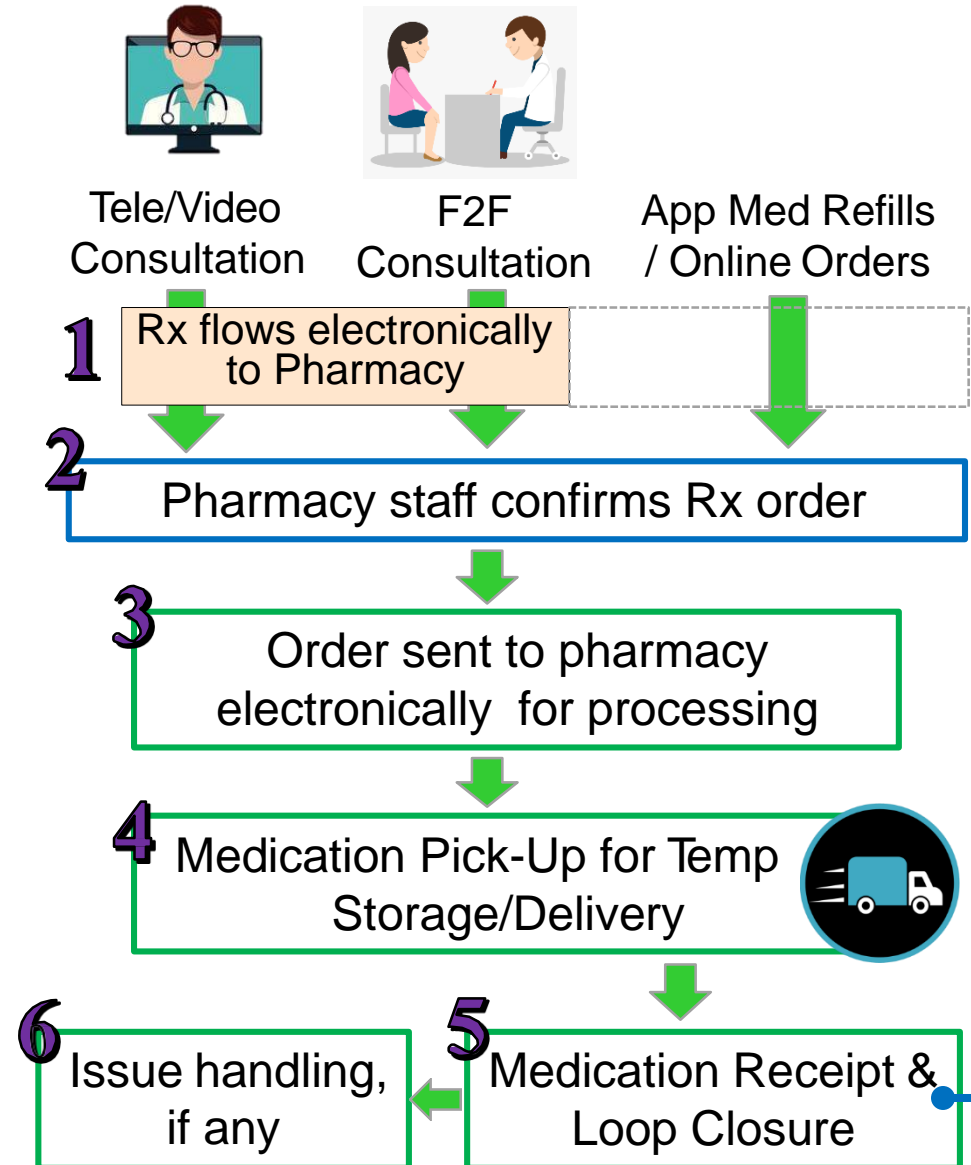| Pharmacy store	In Process	Delivery
• Temperature and humidity mapping 24/7 temperature and humidity tracking with SMS alert • Yearly calibration **Pharmaceutical fridge** • 24/7 Digital and analog recording • 24/7 Security monitoring for excursion and power failure • Yearly calibration • UPS & SOP for cold chain break	• Cold chain item tag • Dedicated fridge sections for Pre-QC and Post-QC items	• Temperature mapping before service engagement, SLA • Only secure lockers with suitable temperature are listed • Dedicated cold chain bag • Thermometer with probe - to display temperature upon delivery

Shared by NHG Pharmacy Central Fill Site

11

Example: Healthcare Model with Central Fill Pharmacy (CFP) support

Enterprise Singapore

Examples of Implementation – Verification of Correct Delivery

Tele/Video Consultation

F2F Consultation

App Med Refills / Online Orders

1 Rx flows electronically to Pharmacy

2 Pharmacy staff confirms Rx order

3 Order sent to pharmacy electronically for processing

4 Medication Pick-Up for Temp Storage/Delivery

6 Issue handling, if any

5 Medication Receipt & Loop Closure

5

- Normal deliveries –
  - Confirmation of recipient name and sign off

- Contactless deliveries
  - Delivery couriers to take a photo of delivery premise's unit number details and verifying recipient name

- SOP that medication parcels are not allowed to be left at doorstep unattended

Shared by NHG Pharmacy Dept

Example: Healthcare Model with Central Fill Pharmacy (CFP) support
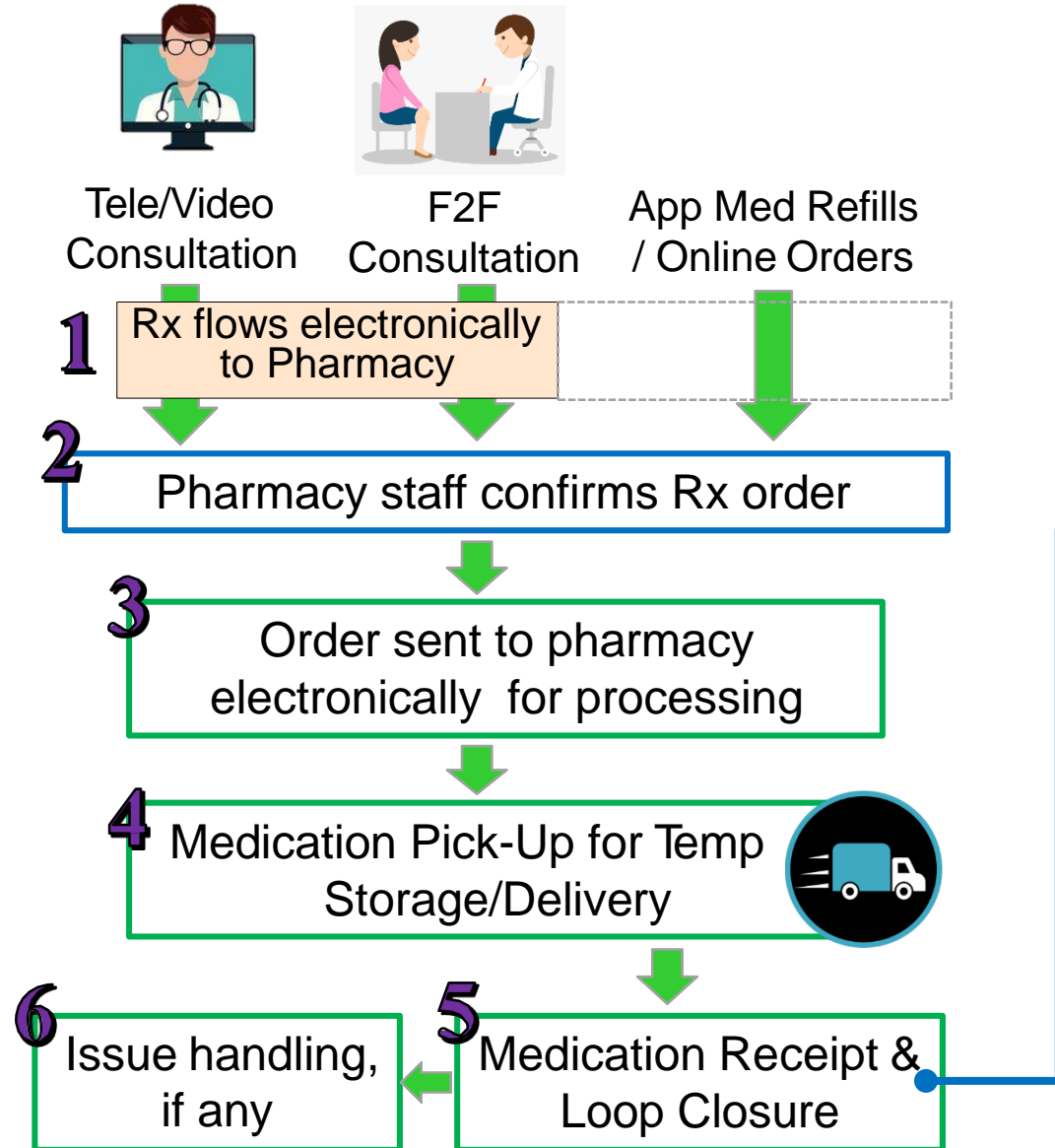
Examples of Implementation – Traceability/Accountability

Enterprise Singapore

1 Tele/Video Consultation | F2F Consultation | App Med Refills / Online Orders

1 Rx flows electronically to Pharmacy

2 Pharmacy staff confirms Rx order

3 Order sent to pharmacy electronically for processing

4 Medication Pick-Up for Temp Storage/Delivery

5 Medication Receipt & Loop Closure

6 Issue handling, if any

Consignment Note

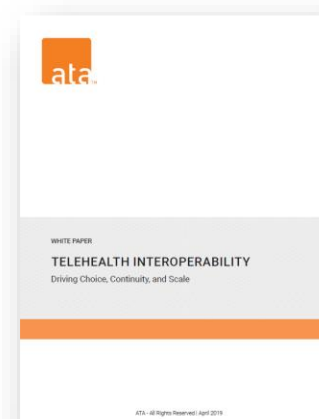*Shared by NHG Pharmacy Central Fill Site*

Guidelines and international standards supporting telemedicine

SG's National Telemedicine Guidelines

WHO

American Telemedicine Association

- ISO 27001 and ISO 27002 – information security management
- ISO 13131 – quality planning for telehealth using risk management process
- ISO 16056 – interoperability between real-time telehealth applications, including audio, video, and data conferencing capabilities

- IEC 60601-1 and IEC 61010-1 – safety of medical equipment
- IEC 62353 – recurrent test and test after repair of medical equipment

Potential standards supporting safe and reliable telemedicine services in Singapore

- Minimum requirements for equipment/solutions used in modern telemedicine services (e.g. wearables, mobile phones, web-conferencing platforms, broadband, cloud providers)

- Data management/privacy linked to electronic health records systems

- E-payment systems

- AI use in telemedicine
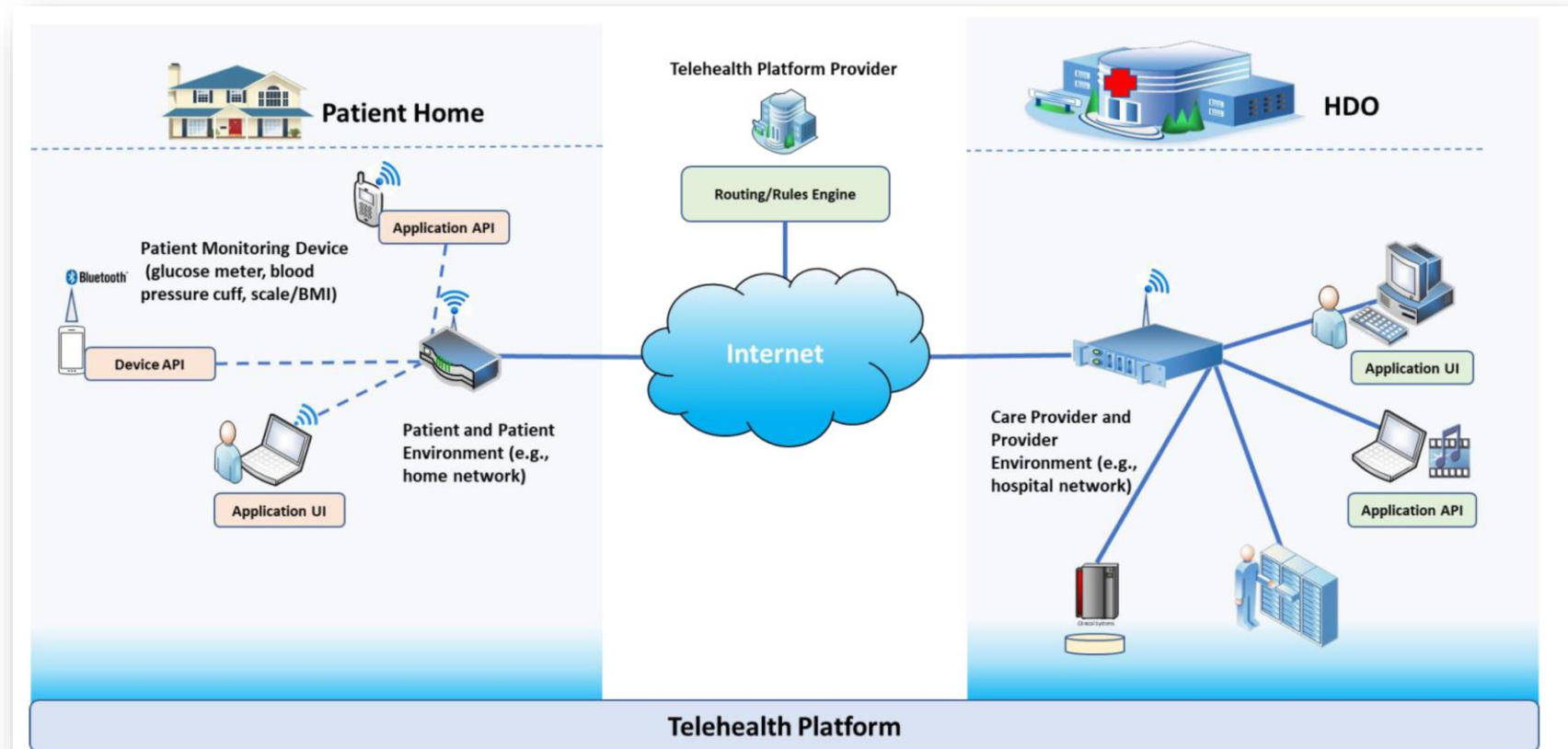
Thank You

www.enterprisesg.gov.sg